

Croatia and Turkey

Competitiveness of the European Pharmaceutical Industry

Presenter: James Copping

Enterprise and Industry DG

Unit F5: Competitiveness in the Pharmaceuticals Industry
and Biotechnology

Commission's Objective

To provide the right environment to secure the long-term investment of the industry in European:

- Health Care
- Research
- Employment
- Industry

Background – Part 1

Traditionally a European success story:

- Employs over 500,000
 - many in high skilled jobs
- Trade surplus of € 36 billion
- Research: investment in European science base of €24 billion
- Source of effective medicines

But ...

Competitiveness is declining

Europe no longer centre of pharmaceutical innovation

➤ 1990 – 2004

Investment in R&D grew twice as fast in the US than EU

➤ R&D moving to US

➤ New challenges from India and China

Background – Part 3

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

What have we done about it?

- Legislation
 - Pharmaceutical Review
 - Competitiveness – key objective
 - Measures to enhance:
 - innovation
 - generics
 - self-medication
- “Bangemann Round Tables”
 - Brought industry together with Member States
- G10 Medicines

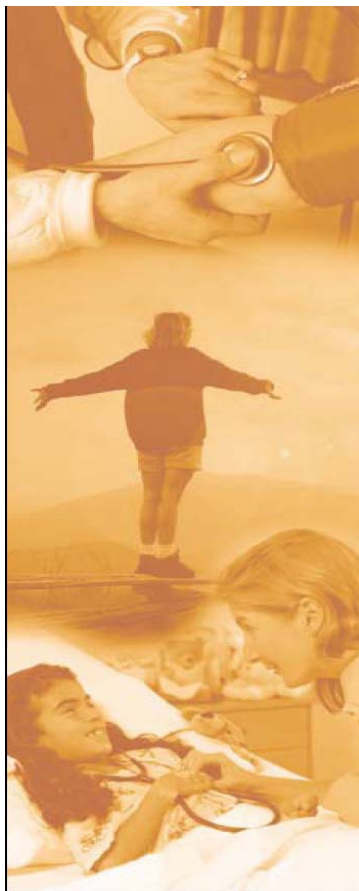
What was G10?

Round-table with 11 high level representatives from Member States, industry, patients & health funds.


To produce recommendations on ways to:

encourage innovation and competitiveness in line with public health objectives

<http://europa.eu.int/comm/enterprise/phabiocom/docs/G10-Medicines.pdf>



07 May 2002

 European Commission

**High Level Group
on innovation
and provision
of medicines**

recommendations for action

G10 MEDICINES - REPORT

What did G10 Recommend?

14 Recommendations covering:

- ⇒ Benchmarking
- ⇒ Competitiveness
- ⇒ Stimulating Innovation
- ⇒ Patents
- ⇒ Enlargement

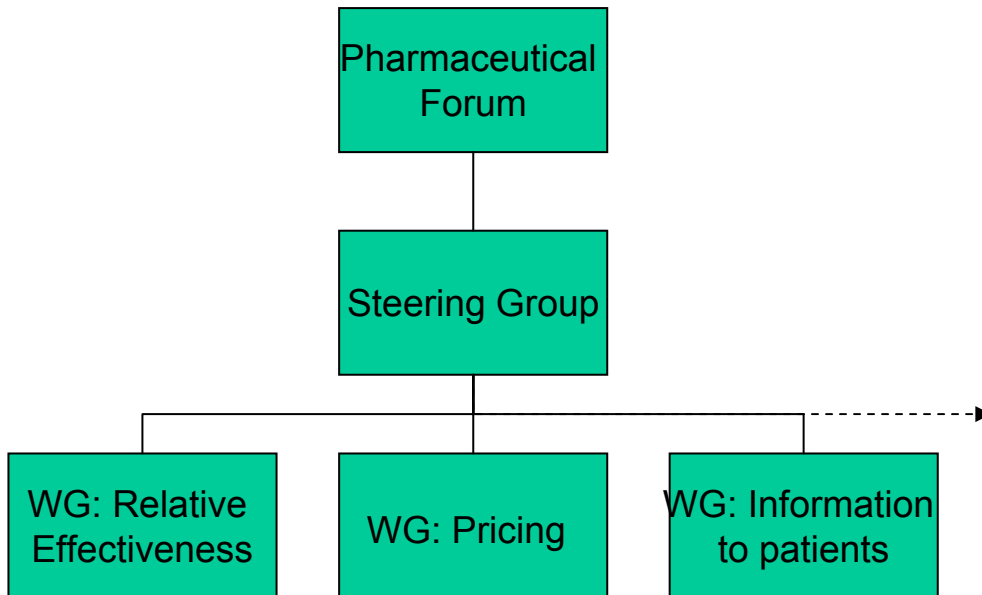
Communication on a Stronger European-based Pharmaceutical industry ...

- Converted advisory report into Commission policy
- Set out exactly how the Commission proposed the G10 recommendations would be implemented

Industry Council – 23 September 2003

- Overall support for the G10 process, in particular:
 - Benchmarking
 - Research
 - Competitiveness of all the sectors important
 - Reflection on pricing & reimbursement

Next Steps



Principles

- Participation of all EU Member States
- Highest level political participation + technical preparation
- Process facilitated by Commission

Pharmaceutical Forum

Pharmaceutical Forum Membership:

- Ministerial level representation from all Member States
- European Parliament
- Senior representatives of:
 - industry (innovative, generic, self-medication, biotech & wholesalers)
 - patients,
 - healthcare professionals (doctors & pharmacists), and
 - health funds

Role:

- Provide strategic direction & political momentum for the work of its working groups
- Supported by a Steering Committee (Stakeholders + 7 Member States + Parliament)

Information to Patients

Need to improve information to Patients, but how?

- Legislation on information drafted before the Internet
- No clear distinction between information & advertising
- Factors to consider
 - Uneven information provision across the Union
 - Potential role of industry
 - Growing demands from patients for better info

Working Group on Patient Information

- Examine options to
 - Provide information to patients in their own language, considering different factors
 - Put medicine information into a broader context
 - Build a central EU information tool
- Build on existing expertise and take account of existing initiatives:
 - Medicine Database (EMEA)
 - EU Health Portal (SANCO/INFSO)

Relative Effectiveness

New, complex, though promising area

- Aims to target limited public funds towards most valuable medicines
- Requires in-depth scientific and clinical assessment
- Available information is usually fragmented
- Absence of standard procedures often leads to duplication across the EU

Working Group on Relative Effectiveness

- Examine how to share experiences and build common approaches
- Double focus possible:
 - Streamline process
 - Examine value of innovation
- Take account of existing initiatives:
 - MEDEV, Baltics, HTA-network, Industry, Transparency Committee

Pricing

Multiple expectations and regulations

- Need to balance 2 expectations on pricing
 - MS duty to keep healthcare affordable
 - Industry's need for a return on investment
- National competence
- Decision-process needs to be in line with Transparency Directive

Working Group on Pricing

- Share and examine experiences with different P+R mechanisms and cost-containment strategies on:
 - Impact on **cost**
 - **Access** to market
 - **Reward** for innovation
- Consider impact of cross-national mechanisms (e.g. international reference pricing)
- Aim for greater certainty to allow to improve climate for investment

Pharmaceutical Forum: Next Steps

- Three year period:
 - Concrete proposals from the working groups for ways forward – beginning with information to patients
 - Seek agreement of proposals in the Pharmaceutical Forum

Pharmaceutical Forum in context

1. Lisbon Agenda 2000 - 2010
2. The Pharmaceutical Forum 2005 - 2008
3. 7th Framework Programme 2007 – 2015
4. Competitiveness and Innovation Programme 2007 - 2015



Thank You!