



European Commission

Enterprise & Industry DG

Competitiveness in Pharmaceuticals – What can we do to put Europe back on Track?

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*Unit F5: Competitiveness in the Pharmaceuticals Industry and
Biotechnology*



Challenges

- Decline in competitiveness vs. USA
- Growth of new competitors e.g. China & India
- Ever increasing healthcare budgetary pressures
- Fragmented market
- Enlargement



Challenges for the Pharma Sector

America has replaced Europe as the world's centre for innovation:

1960s: Europe invented 65% of all medicines; **Now 35%**

1990s: Europe spent 30% more than the US on R&D. **Now the situation is reversed.**

Does this matter?

Yes!

- Social: employment
- Economic: trade surplus
- Health: major contribution to treatment & prevention
- Research: investment in European R&D & EU Science Base
- Lisbon Objectives



Conclusions

- Competitiveness of the European-based pharmaceutical industry remains at the top of the agenda
- Support for biotechnology important part of the competitiveness strategy
- Both critical to success of Lisbon

What have We Already Achieved?

Revision of the regulatory framework

- Longer and harmonised data exclusivity,
- Waivers and deferrals for a number of fees,
- Easier access to scientific advice from the Medicines Agency (EMA),
- Special incentives for companies developing orphan drugs and finally
- Administrative support by establishing a special “SME Office” within the EMA.

So What are we Doing About it?

- FP7
- CIP
- post-G10 Medicines



Building the Europe of Knowledge

Commission Proposals for the 7th
Research Framework Programme
(2007 – 2013)

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Total proposed budget € 73.2 billion
Health (€ 8.3 billion)



What's new in FP7?

Some main features:

- Doubling the FP7 budget compared to FP6
- Responding to the needs of European industry by
 - Increased industry involvement (Technology Platforms)
 - Simplification of FP7
 - Increased support for SME's research

A Technology Platform Innovative Medicines – Why???

Long term objective

- Increasing the competitiveness of the European pharmaceutical industry
- Making Europe more attractive for pharmaceutical R&D.
- Removing major bottlenecks in drug development
- Improving access to innovative medicine

What's the Innovative Medicines Platform all about?

- Increasing effectiveness of public and private investment in research and development
- Coordinating of clinical trials at European scale
- Fostering of innovation, competitiveness and productivity
- Shortening drug development times

Why a new Programme for Competitiveness and Innovation?

Three elements seem to be particularly relevant:

- Entrepreneurship
- Access to financing
- Special assistance to SMEs



Next Steps – G10 Pharmaceutical Forum

Most important remaining G10
issues

- Pricing/Pricing
- Relative effectiveness
- Information to patients