Public Private Partnership and Better Information on Medicines

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Long History

Long held recognition of need to improve information to patients:

- Legislation on information drafted before the Internet
- No clear distinction between information & advertising
- Suspicion over role of industry
  - Fear of Direct-To-Consumer Advertising
- Growing demands from patients for more & better info
- Increasing pressure on national healthcare budgets

Previous attempts

1999 – Stock-take of national approaches to advertising/information

2002 – Workshops on distinction between advertising & information

2002 – G10 discussion on PPP

2003 – Failure of Commission Article 88 proposal on information

Current Position - Regulation

New Legislative Framework (Nov 2005):

- Introduction of Braille packaging (Art 56a)
- Restructuring of patient leaflets (Art 59)
- Mandatory user-testing of leaflets (Art 59)
- Readability Guidelines (Art 65)
- Review of patient information in Europe (Art 88a)

Current Position - G10 Medicines

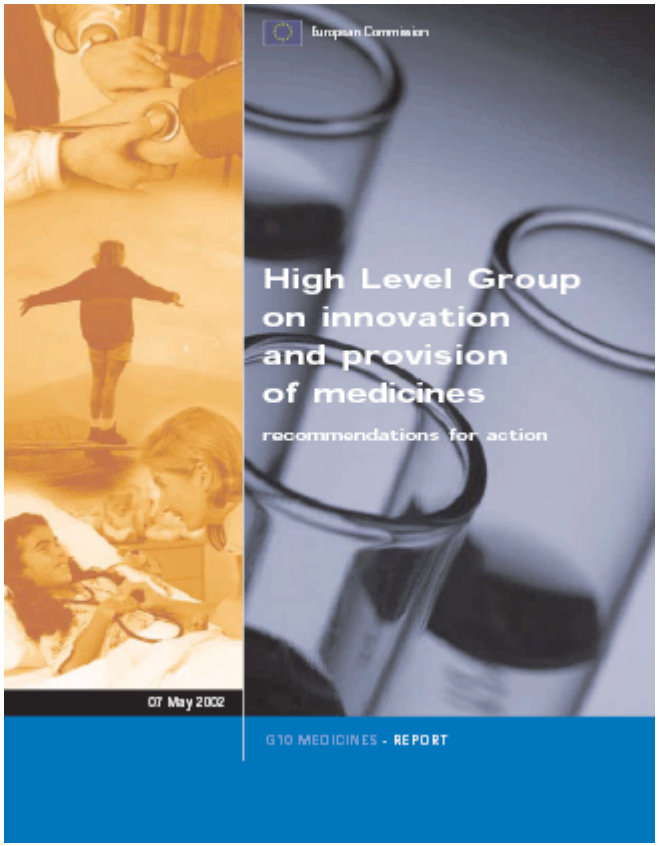
Small High Level Group

- Established 2001

- Member States, industry, patients & health funds

- 14 Broad Recommendations

- Final meeting in June 2004



G10 Medicines

G10 Recommendation on Information:

“Establishment of a collaborative public-private partnership involving a range of interested parties. The information should be carefully piloted and evaluated to assess the extent to which it meets the needs of patients with these conditions.”

May 2002

Commission response

"To increase public confidence in patient information on medicines, the Commission will reflect on establishing a collaborative **Public Private Partnership** involving a range of interested parties including **representatives from public authorities, industry, health funds, health care professionals and patient groups**. It could take the form of a small body that would be able to advise and monitor the quality of the information already provided and produce guidelines in specific areas **to support the work of national and Community regulatory authorities**."

July 2003

Council Opinion

“WELCOMES the implementation of actions concerning public-private partnerships to develop approaches to validating, and ensuring the quality of non promotional information already provided to patients, in particular, in collaboration with pharmaceutical companies and health professionals, to ensure quality in the provision of non promotional information to the public through internet sites.

The Commission should ensure that this builds on **existing European initiatives in e-health**, such as the development of quality criteria for internet websites, and incorporates public and private sector initiatives.”

December 2004

So What's Happened?

2004 - discussion on way forward taking account of:

- National Competence
- Compatibility with EU legislation
- Compatibility with existing EU initiatives
- Need for practical solutions
- Pharmaceutical Review requirement

Proposal - Objectives

Commission’s objectives:

- To add value to national & EU projects
- Provide information to patients in their own language
- Build on existing expertise
- Put medicine into a broader context

Proposal – Likely Scope

- Public Private Partnership:
  - regulators, patients, industry & other stakeholders
  - examine options within fixed period
  - take account of existing initiatives:
    - EuroPharm Database (EMEA)
    - EU Health Portal (SANCO)
  - Make recommendations to the Commission

Next Steps

- Commission to decide on final scope shortly
- Membership to be decided in consultation with DG SANCO
  - will include a patient representative!
- Hope Partnership to start in Autumn 2005

Conclusions

- First step to review the way we approach patient information
- Attempt to build confidence between stakeholders
- Provide basis for statutory review of patient information in 2007
- Part of the new industrial strategy for the pharmaceutical sector

Thank you!