Challenges and Key Success Factors for the Biopharma Industry in Europe

Alexandre Delacoux
Executive Director of EBE
Why is Innovation Important?

- Addressing the fundamentally unmet medical needs and investing in patient care
- Improving the quality and efficiency of European healthcare systems
- Nurturing Europe as an attractive territory for added value industrial and R&D investments
- Leveraging the technological and scientific advancements

Convergence of diverse industries (biotechnology, pharmaceuticals, diagnostics, devices, telcos) paves the way for a medical revolution focused on patient care rather than on treating diseases
We operate in a risky and long-term biopharma business

An unrelenting selection process
A dramatic drug discovery process from research to manufacturable product

Very long development process
It can take up to 10 years for a new product to come to market
Innovation in biopharmaceuticals has not met expectations and delayed access to treatment compound the issue.

Falling NMEs, rising costs
Despite increasing R&D expenditure, the number of innovative medicines is dropping.

Delay from authorisation to market access
Considerable variability in time from market authorisation to effective access.

Source: Modified from 2010 CMR International Pharmaceutical R&D Factbook.

Source: Comparator report on patient access to cancer drugs in Europe (2009).
It is critical to encourage innovation

★ European programmes are important
  • IMI is addressing research bottlenecks
  • The FP is addressing research needs

★ Financial crisis has worsened the financing innovative SMEs
  • Lack of start-up capital
  • Numbers of Venture Capitalists decreasing
  • Some countries have raised no biotech money in 2010 (France)

★ The regulatory framework is evolving: EMA/HTA relation & balance

★ Organising market access in the EU with 27 Member States is required to accelerate access of innovation to patients

★ Patent and data protection are key in our industry
We all have a role to play to bolster innovation

• Industry’s role in bringing new targeted products to market and active work with research institutions
• EMA’s heightened role on safety, efficacy and quality
• Governments to fund innovation and to clarify role of HTAs
THANK YOU!