



V Foro Europeo de Politica Farmaceutica

Antonio Tataranni, MD
Madrid, 25 May 2009



sanofi aventis

L'essentiel c'est la santé.



Background on EU fundamentals

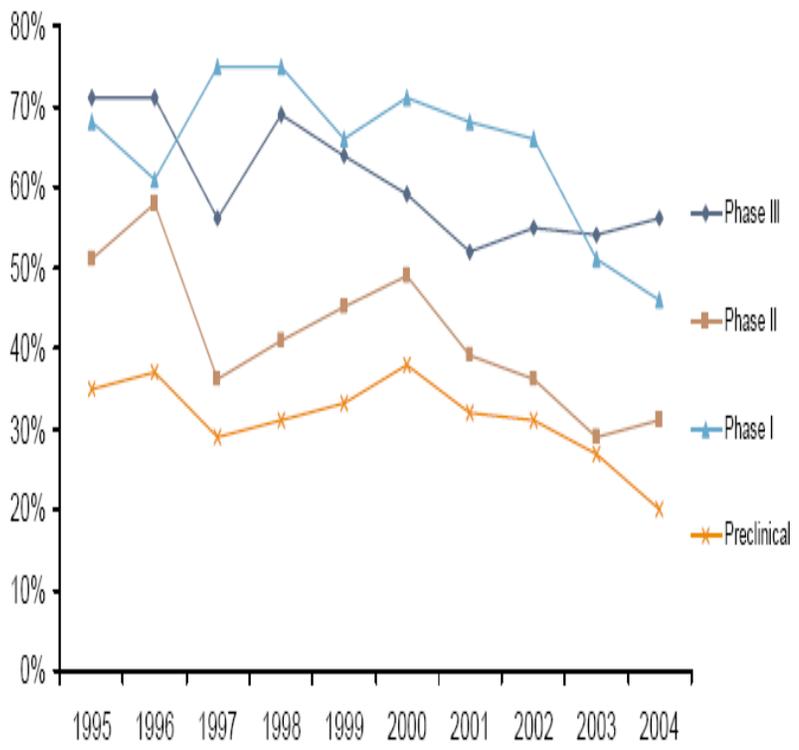
- World's 2nd largest health care market
 - Ageing population (20% > 65 yrs) drives burden of disease and prevention need
 - Sustained need for proven innovation to respond to unmet patient needs (in particular prevention and end of life treatments)

- Highly developed social systems with unmatched reimbursement levels
 - Increasing price pressure on Rx drugs
 - Struggle to accelerate low cost alternatives for standard of care to cover basic needs

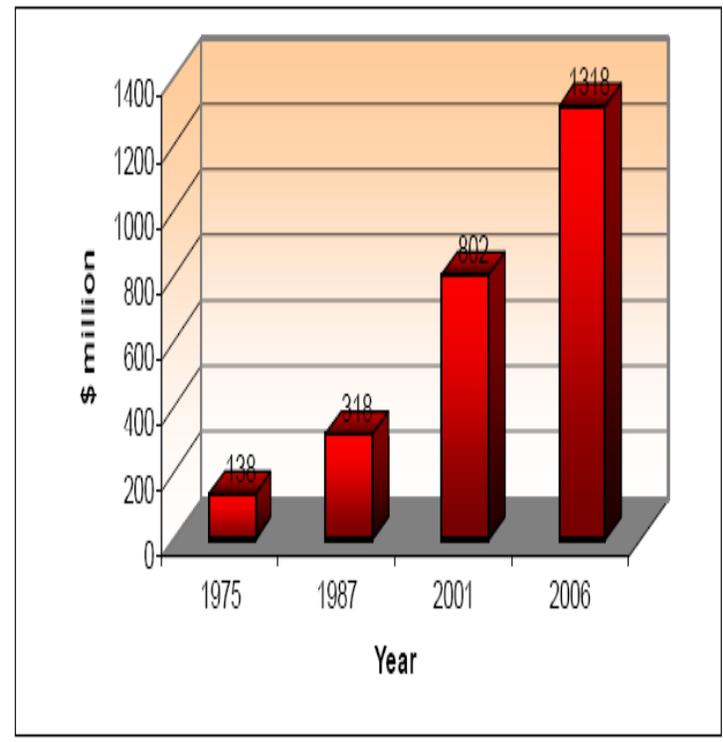
Innovation still a key driver: so what is wrong ?

- R&D success rate is declining

- R&D Cost is increasing



Source: AVOS



Estimated full cost of bringing a new chemical or biological entity to market (\$ million – year 2005 \$) – Source: J.A. Di Masi and H.G. Grabowski, 'The Cost of Biopharmaceutical R&D: Is biotech Different? Managerial and Decision Economics 28 (2007): 469-479

Why is this happening?

CHALLENGE

● An inherently risky endeavor

- ▶ 4 out of 5 (80%) potential products that start *clinical* development fail to make it to market
- ▶ At least 50% of drugs that undergo *Phase 3* trials turn out to be too unsafe or not effective enough for marketing: benefit/risk calculus fails

● Task of Innovation harder, hallmark → unpredictability

- ▶ “Low hanging” fruit has been picked
- ▶ Regulatory processes can seem impenetrable and unresponsive

OPPORTUNITY

● Many serious diseases afflict our populations and are waiting for quicker/more accurate diagnoses and better treatments:

- ▶ autism, addictive disorders, Alzheimer's disease, HIV/AIDS, bipolar disorders, cancer, cystic fibrosis, heart diseases, diabetes, morbid obesity, multiple sclerosis, muscular dystrophy, rheumatoid arthritis, osteoarthritis, systemic lupus, schizophrenia, stroke, and many more

● Advances in Basic Science: Best yet to come?

- ▶ Genomics / Proteomics, Nanotechnology, Biomedical Info Technology
- ▶ More effective, more targeted, individualised medical therapy

....R&D of new drugs fails because of

- **Lack of efficacy**
- **Identification of safety signals**
- **Uncertain value proposition**



Shift to stratified medicine

- **Switch from population-based, empiric medicine, to medicine based on personal determinants**
 - ▶ A new model based on a larger portfolio of targeted treatments – more effective & predictable – not one-size-fits-all drugs
- **Switch from medical choices based on statistical probabilities of success, to those based on pre-determined pathways and mechanisms that define success for a specific patient**
 - ▶ Stratified medicines that demonstrate a clear superiority to alternatives treatments for a smaller “niche” patient population
 - ▶ Greater efficacy, higher adoption rates allow higher price and high revenues
- **Stratified medicines derives from the fusion of pharma and biotech expertise... “Life sciences and biotechnology are widely recognized to be (...) the next wave of knowledge-based economy, creating new opportunities for our societies and economies” (1)**

1. The European Commission statement in 2002 a strategy document (2002) reproduced in A new global strategy for the life sciences in Europe, Luc van Dyck, EMBO reports, vol 6, n° 3, 2005



Biomarkers



Reliable biomarkers

- ▶ Facilitate more intelligent and unbiased enrichment trial designs
- ▶ Guide dosage determinations
- ▶ Facilitate more accurate and rapid measurements of a candidate product's potential efficacy
- ▶ Lead to earlier indicators of the severity of emerging toxicity



Biomarkers issue

- ▶ Imperative that a biomarker for regulatory decision-making be supported by a broad scientific consensus.

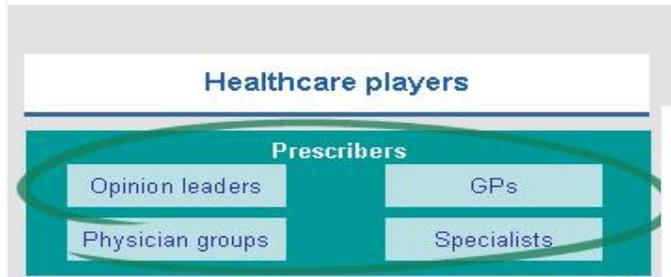


....R&D of new drugs fails because of

- Lack of efficacy
- Identification of safety signals
- **Uncertain value proposition**



Change: pharma industry and its key customers

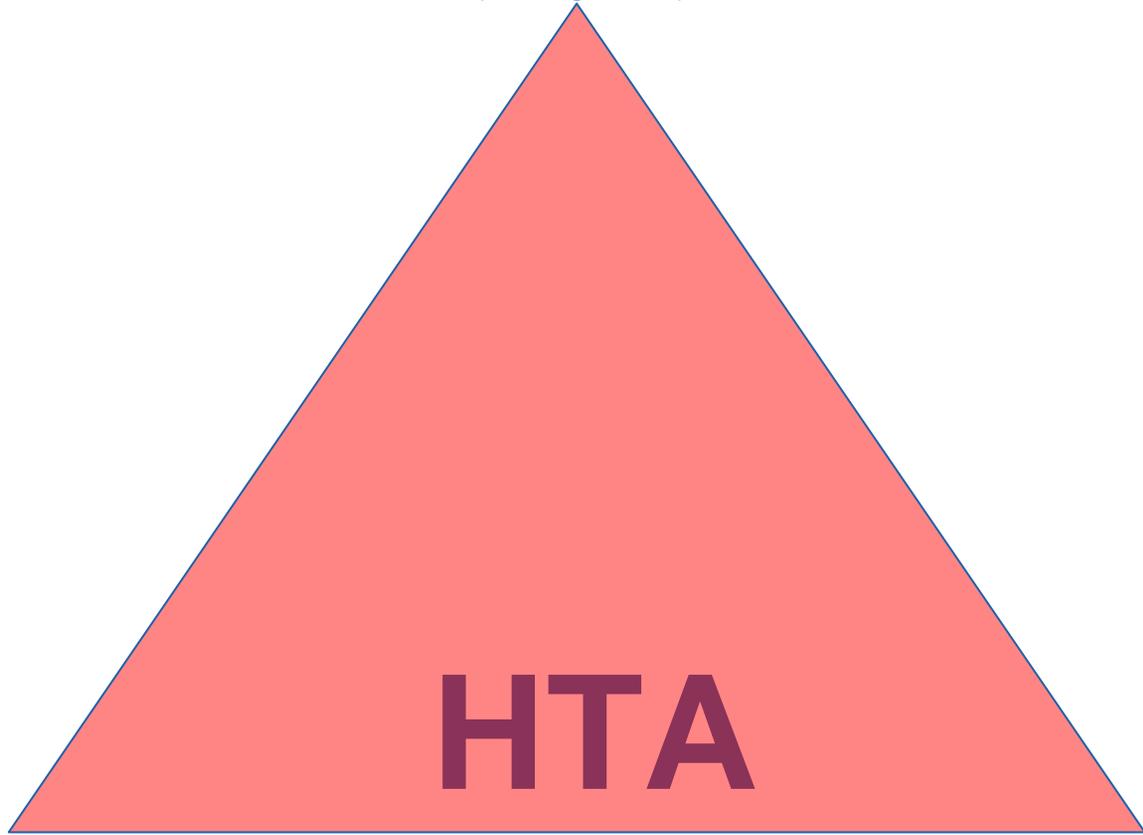




The evolving field of Health Technology Assessment

EUnetHTA

(>40 Agencies)



NICE
IQWIG
SBU-LFN/TLF

INAHTA

(>60 Agencies)



Evolution from traditional Pharma business towards Integrated Healthcare Company model

- **Continue to increase innovation in R&D**
 - ▶ Intelligent allocation of resources between internal and external partnerships
- **Adapt to future challenges**
 - ▶ Diversification and external growth opportunities
 - ▶ Improve access to medicine for a wider population
- **Collaborate with HA to identify novel and more attractive market access solutions**
 - ▶ Risk sharing agreements
 - ▶ Outcomes guaranteed
 - ▶ other



Conclusion

- Holistic disease management

- Healthcare expenditure as an investment, not a cost

- Growing importance of public/private collaborations in R&D

- An example: the Innovative Medicines Initiative

- Key role of policy-makers

- Shape a shared understanding of value and how to reward innovation