



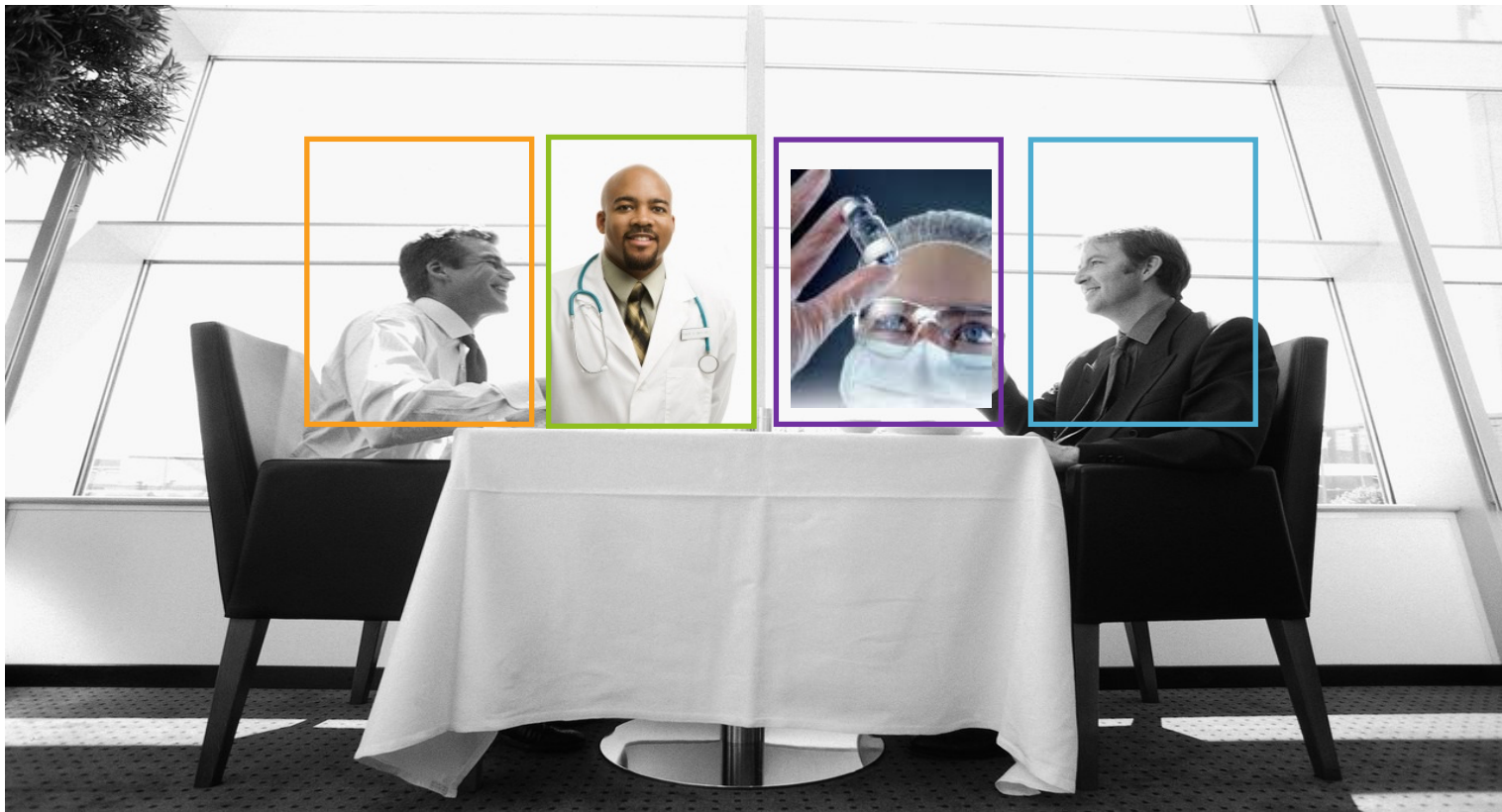
17th February 2011

Value-based healthcare What can industry realistically deliver?

Thomas B. Cueni, General Secretary Interpharma, Chair ESPC EFPIA

Healthcare – Dinner for Four! A Balanced Meal

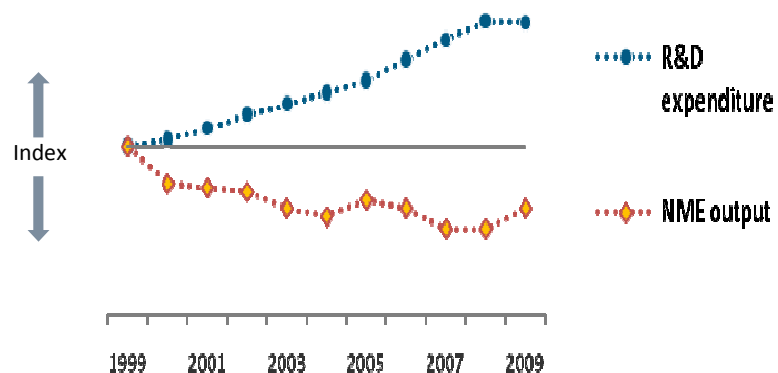
Patient Need? Dr Need? Industry Needs? Payer Needs?



Challenges in R&D

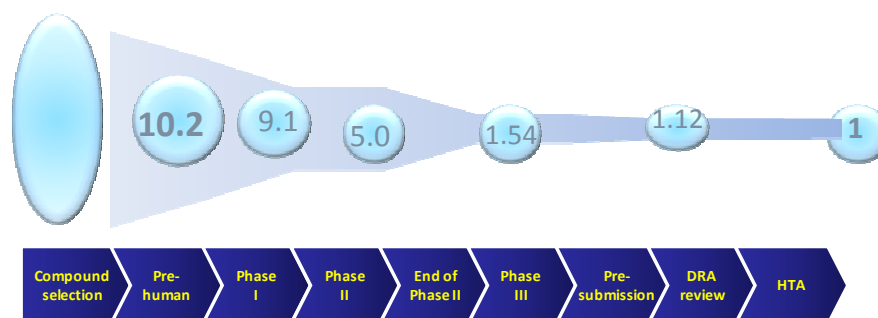
Falling NMEs, rising costs

Despite increasing R&D expenditure, the number of innovative medicines is dropping



Late stage failure

What is the impact of failure of licensed NMEs to achieve reimbursement?



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

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Should we focus on priority medicines? What about innovation incentives?

- 1. Antibacterial drug resistance**
- 2. Pandemic influenza**
- 3. Cardiovascular disease secondary prevention**
- 4. Diabetes**
- 5. Cancer**
- 6. Acute stroke**
- 7. HIV/AIDS**
- 8. Tuberculosis**
- 9. Neglected diseases**
- 10. Malaria**
- 11. Alzheimer disease**
- 12. Osteoarthritis**
- 13. Chronic obstructive pulmonary disease (COPD)**
- 14. Alcohol use disorders**
- 15. Depression in the elderly and adolescents**

Source: Priority Medicines for Europe and the World Project
Value-based healthcare – What can industry realistically deliver?

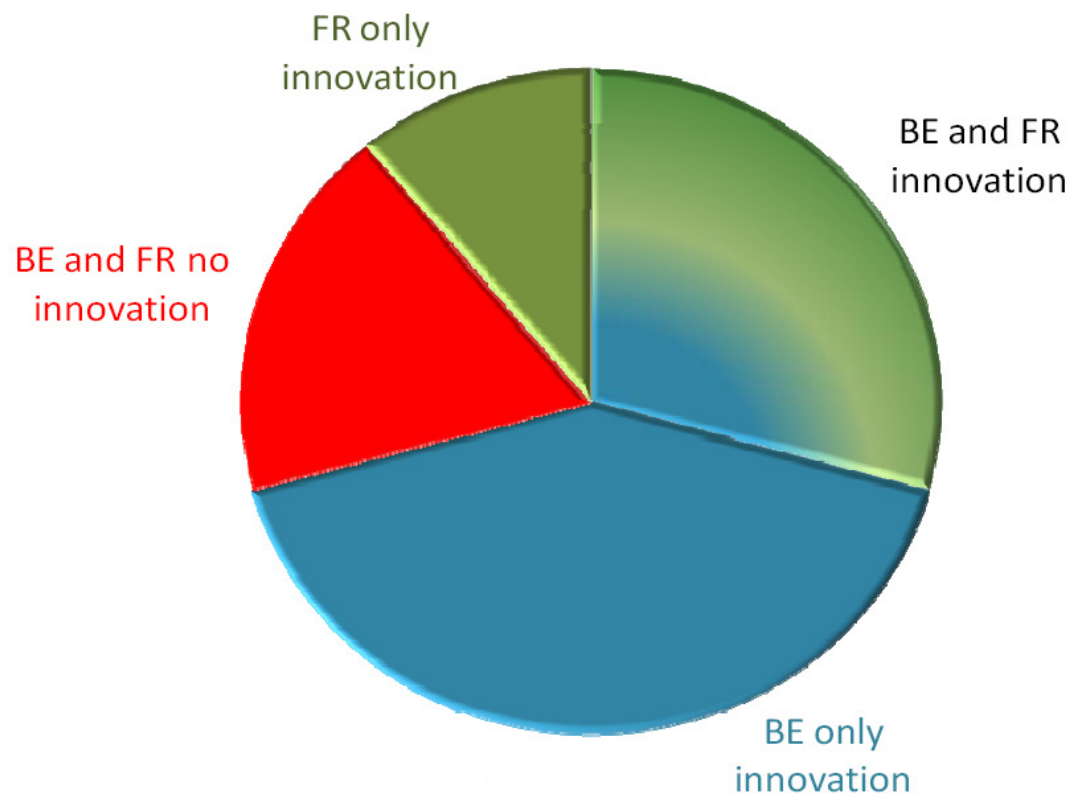
Characterisation of the Value of Innovative Medicines

Value of medicines can be structured in 3 main areas:

- 1. “Therapeutic/Clinical” benefits** refer to those new medicinal products, which are able to treat or to prevent, in all patients or in specific patient groups, diseases lacking (adequate) treatments or diseases already treated with pre-existing medicinal products but with clinical or safety advantages.
- 2. “Quality of Life” benefits** refer to those new medicinal products, which, compared to the existing ones, are able, in all patients or in specific patient groups, to provide quality of life gains.
- 3. “Socio-economic” benefits** refer to those new medicinal products, which, compared to the existing ones, are (also) able to offer benefit on a higher-level for society (e.g. related to public health or public budgets).

Source: Final Conclusions and Recommendations of the Pharmaceutical Forum, High Level Pharmaceutical Forum 2005 – 2008

Countries have a different understanding of 'added value responding to unmet medical needs'



Source: Ministerial Conference "Innovation and Solidarity on Pharmaceuticals", Results of a Comparative Study on Innovation and Conclusions of the Background Report, Jo DE COCK, National Institute Health & Disability Insurance (NIHDI), Brussels, 23-24 September 2010

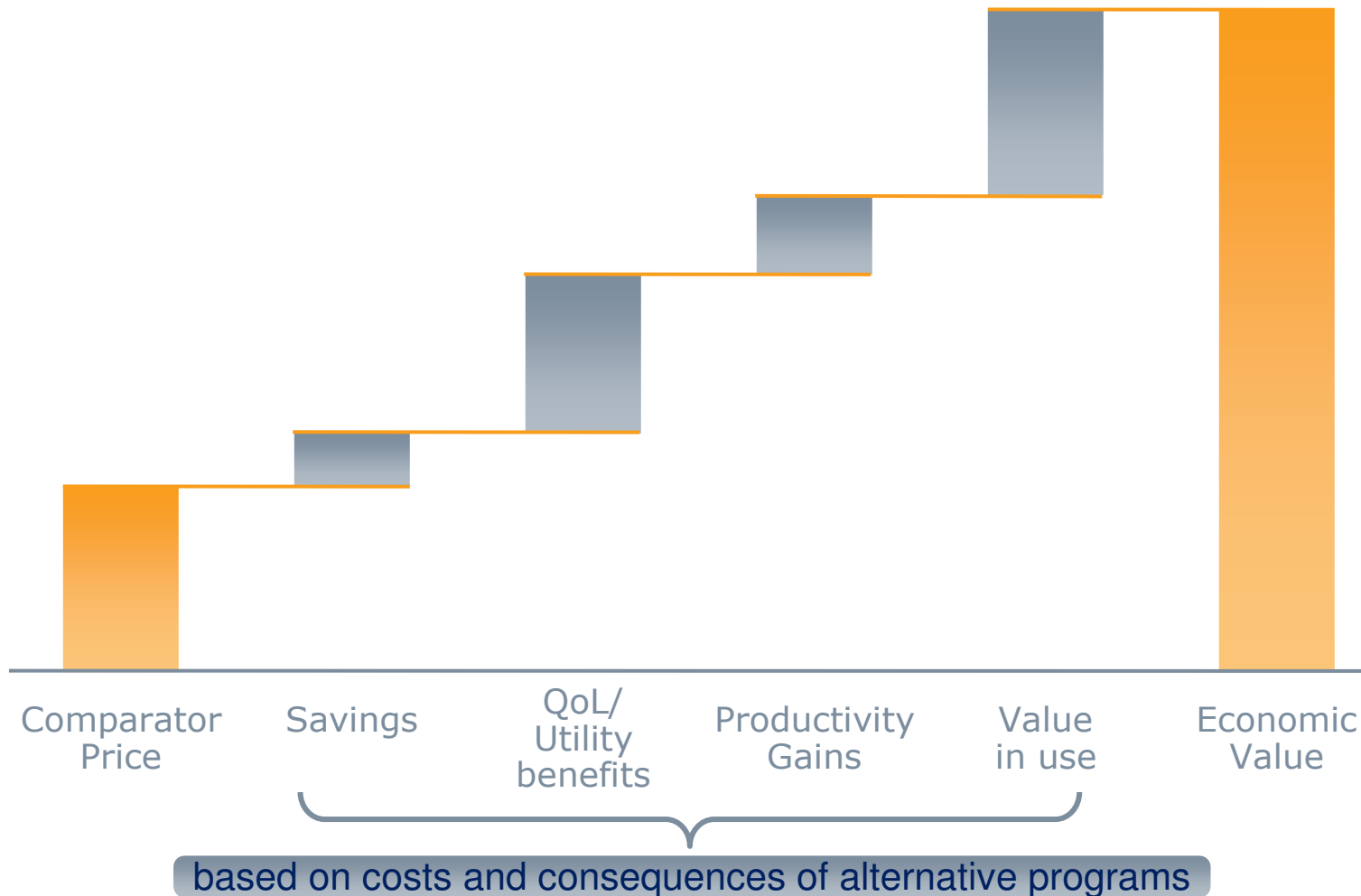
Value of innovation – NICE Citizens Council

What makes an innovation valuable to you?

1. It increases quality of life	26
2. Other innovations may be developed from it in the future	11
3. A large number of people will benefit from it	10
4. It saves your life	9
5. It increases life expectancy	9
6. It meets a previously unmet need	6
7. It prevents a condition	5
8. It cures a condition	5
9. There are few other treatment options	1
10. It reduces risk to the patient	0
11. It has a one-off cost rather than ongoing costs	0

Source: Report on NICE Citizens Council meeting: Health Innovation and Value, May 28-30, 2009

An industry perspective of understanding the value of a drug



How to put a value to a new medicine?

1. Competitive market price

2. Therapeutic comparison (=value based pricing)

- Clinical relevance (added therapeutic value): Lower mortality, faster cure, improved quality of life, better compliance, better outcomes
- Cost effectiveness: Faster re-integration, in-patient costs/out-patient costs, cost-benefit

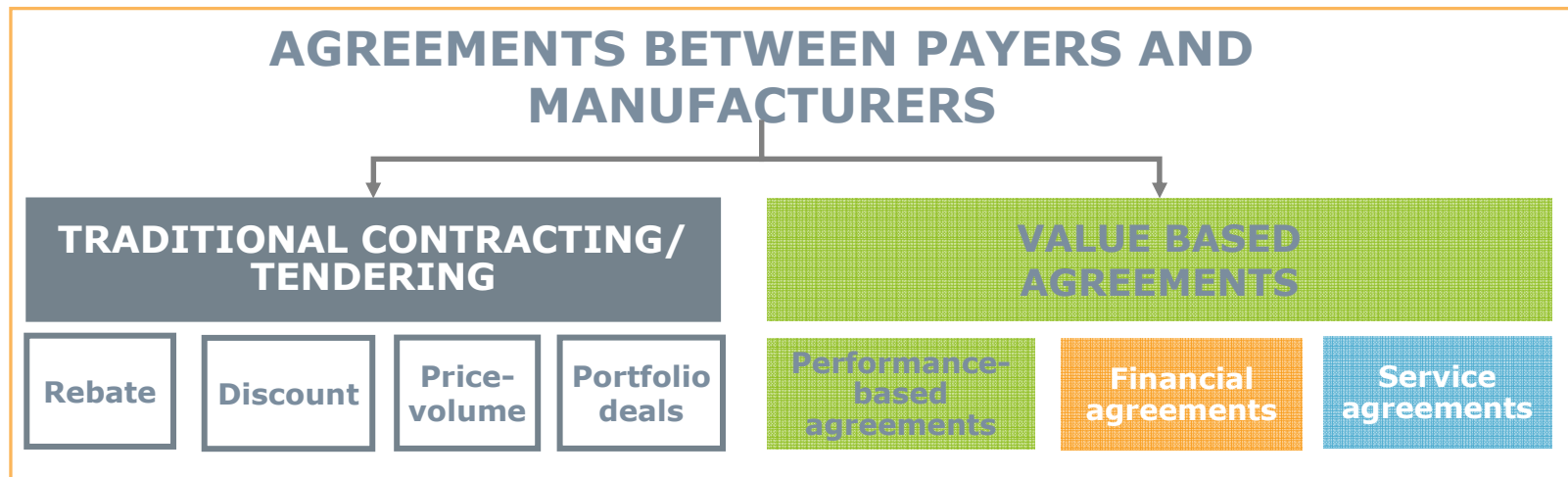
3. Country baskets (=political value)

- Not higher than average of...
- The average of the three lowest...
- The lowest of any...

Guiding Principles for good practices in Pricing & Reimbursement policy

- 1.Ensure timely access to valuable innovation**
- 2.Provide affordable medicines**
- 3.Ensure equal availability of medicines**
- 4.Limit price control to where it is needed to contain public budget**
- 5.Set-up a consistent package of supply and demand-side measures**
- 6.Create the right environment for price competition**
- 7.Set expectations**
- 8.Recognise innovation / Be consistent when giving reward**

Trading off



- | | |
|------------------------------------|--------------------------------------|
| ■ Price is only relevant attribute | ■ Value attributes are most relevant |
| ■ Value of innovation is ignored | ■ Value of innovation is secured |
| ■ Impacts future product values | ■ Supports future product values |
| ■ Results in downwards spiral | ■ Results in reassurance of value |

Short term interests of stakeholders might impact long term strategies

Source: IMS Health, 2009

Can we make coverage decisions predictable?

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Innovative Pricing Models have definite benefits ...

- Broaden patient access
- Drive business and enhance market penetration
- Protect the list prices while at the same time overcome limitations in data availability
- Increase affordability in self-pay, high co-pay markets
- Establish a partnership dialogue with payers

... **but generate their own challenges**

- Requires new skills on both parts, industry and payers, to evaluate terms and in particular risks
- Significant complexity for data collection and monitoring
- May not be compatible with national P&R regulations (e.g. Spain, Sweden, Finland, Romania, Korea)
- Ensure confidentiality to prevent price erosion

Conclusion

- Pharmaceutical innovation brings benefits to patients and wealth to society
- Price pressure, cross-referencing, reduced access
- If society is not willing to pay for uncertainty, it may not get the innovation it wants
- Innovative pricing models under confidentiality agreements are being implemented to broaden access
- When carefully selected such models create a win-win with enhanced and timely access for patients
- Dialogue and openness is needed from governments and industry
 - Value-based pricing means significant reward for breakthrough innovation and incremental reward for incremental innovation
 - Need more flexible arrangements
- A challenge for us all...

Thank you

17th February 2011