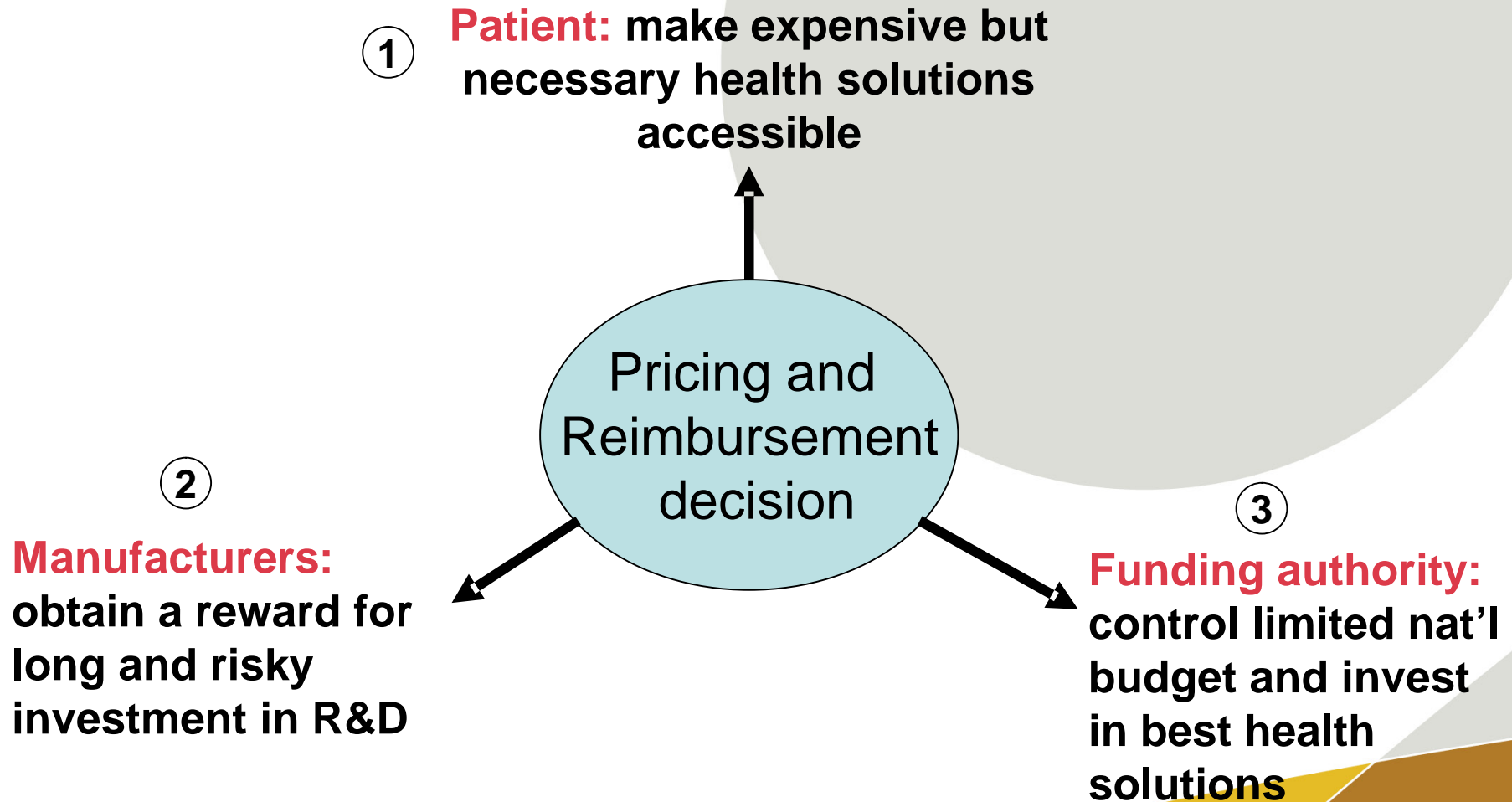


Outcomes of the Working Group on Pricing and Reimbursement

The Pharmaceutical Forum
Delivering for Patients
25 March 2009, Brussels

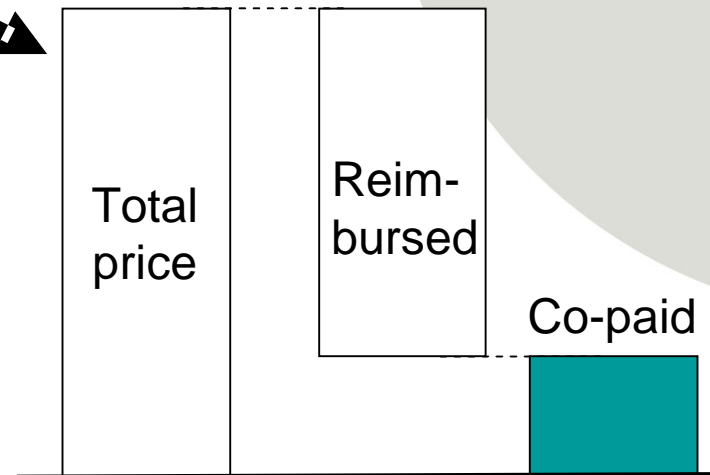
EXPECTATIONS FROM A PRICING AND REIMBURSEMENT DECISION



P&R-DECISIONS DEFINE ECONOMIC ACCESS / AFFORDABILITY FOR PATIENTS

Positive list:

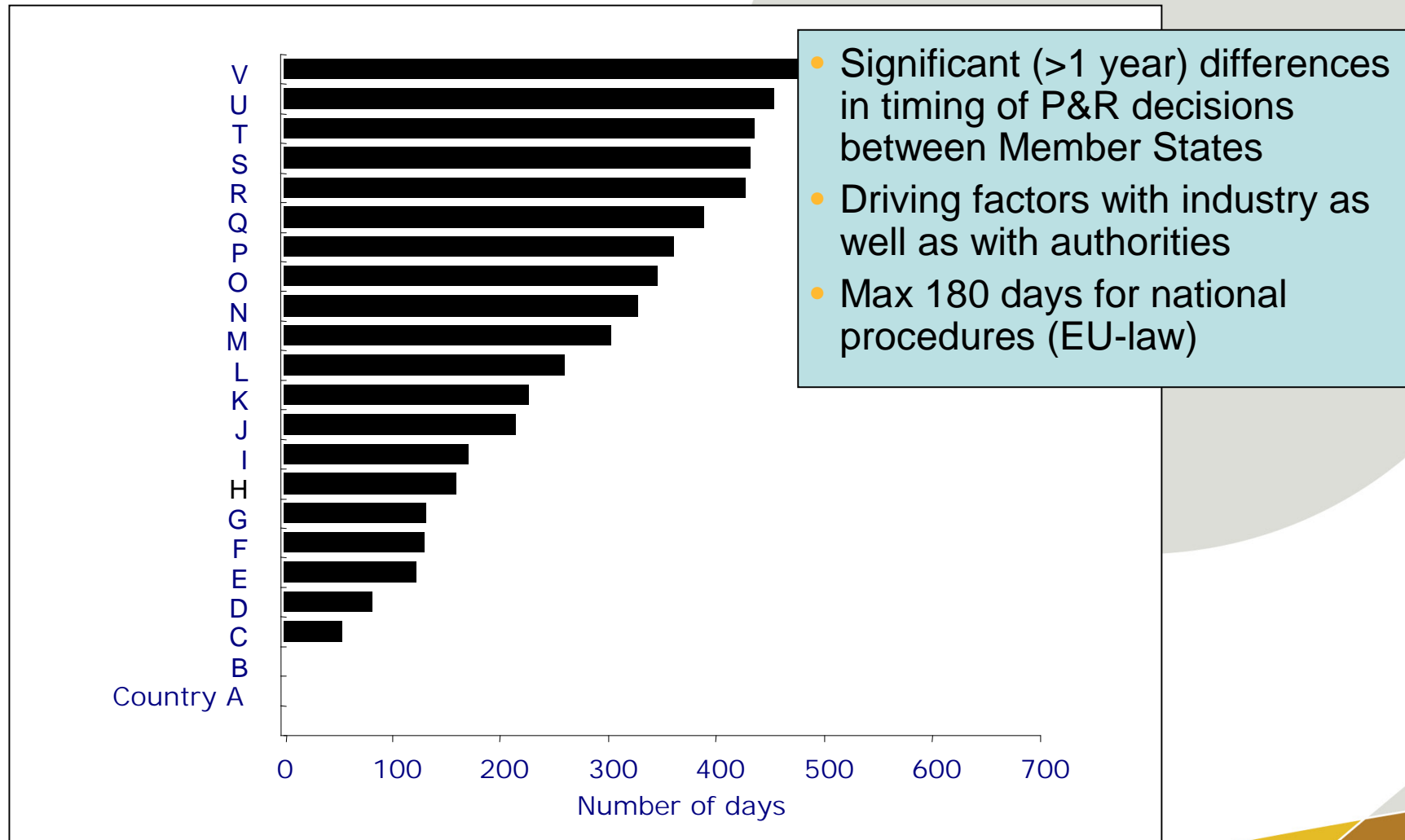
- XYZ
- ABC
- DEF
- ...



- Patient co-payment
 - § Inclusion + list
 - § Total price
 - § Level of reimbursement
- Consider
 - § Type of disease
 - § Patient's wealth
- Variation EU-MS
 - § Reimbursement from 50 to 90%
 - § Different socio-economic status
 - § Existence additional insurance

MOMENT OF P&R DECISION DEFINES AVAILABILITY

Time between Market Authorisation and P&R decision



FINAL RECOMMENDATIONS OF THE HLPF

- Recommendation 7: **Access** to medicines for EU citizens
 - § Fasten access, apply Directive 89/105/EEC
 - § Improve availability in small markets
 - § Ensure equal access to orphan medicines
- Recommendation 8: Expect, identify and **reward** valuable **innovation**
 - § Set common and clear expectations
 - § Be consistent with recognition and reward
 - § Align all elements in national P&R systems
- Recommendation 9: **Optimal use of resources**
 - § Keep the patient focus
 - § Align all elements of P&R practices
 - § Exchange experiences between Member States
 - § Further development of knowledge

KEY DOCUMENTS ADOPTED IN THE WG PRICING

- “Guiding principles” for good practices implementing a pricing and reimbursement policy

- 1. On Access for patients:
 - § Ensuring access to medicines in small national markets in Europe
 - § Improving access to orphan medicines for all affected EU citizens

- 2. On Reward for innovation:
 - § Characterisation of the value of innovative medicines
 - § From assessing innovative value of pharmaceuticals to pricing and reimbursement decisions

- 3. On Control of expenditure:
 - § Risk sharing practices and conditional pricing of pharmaceutical
 - § The Toolbox exercise

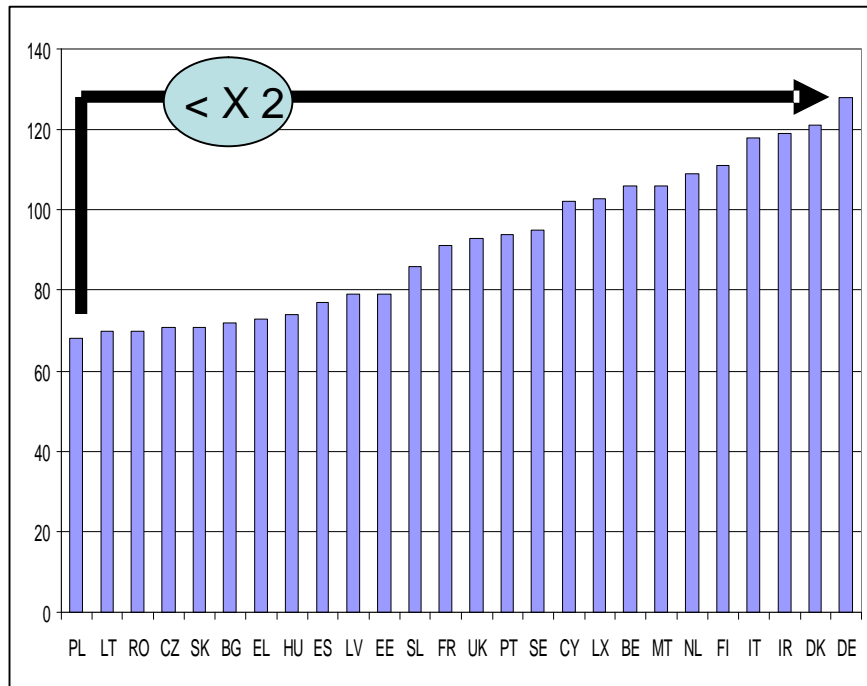
See: http://ec.europa.eu/pharmaforum/pricing_en.htm

KEY ELEMENTS TO IMPROVE ACCESS TO MEDICINES

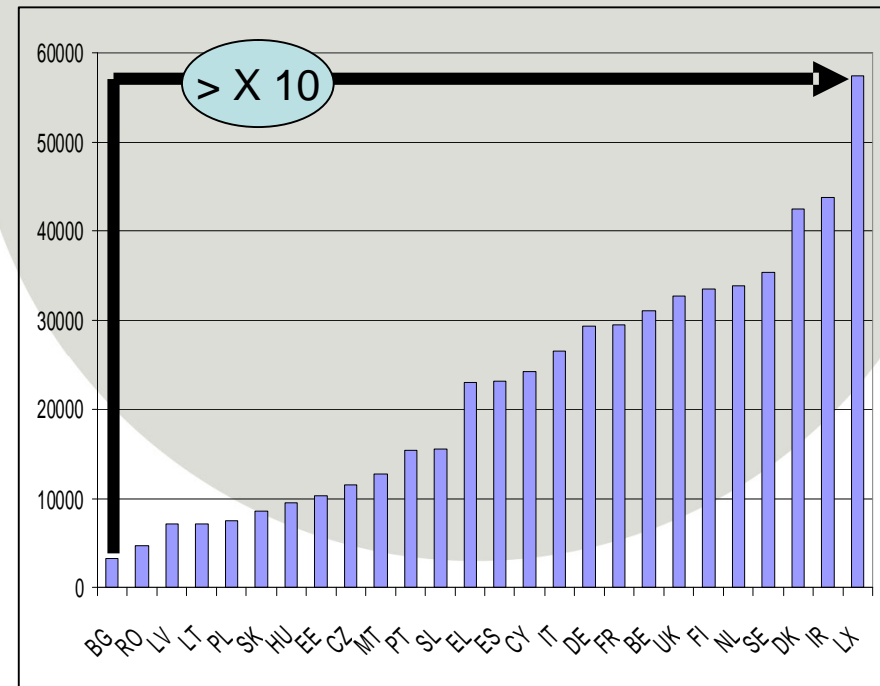
1. Affordability differences over the European Union
2. Good use of generics policies
3. Good use of conditional pricing/risk sharing practices
4. Access to orphan medicines
5. Availability in small Member States

AFFORDABILITY HAS A TRANS-EUROPEAN DIMENSION

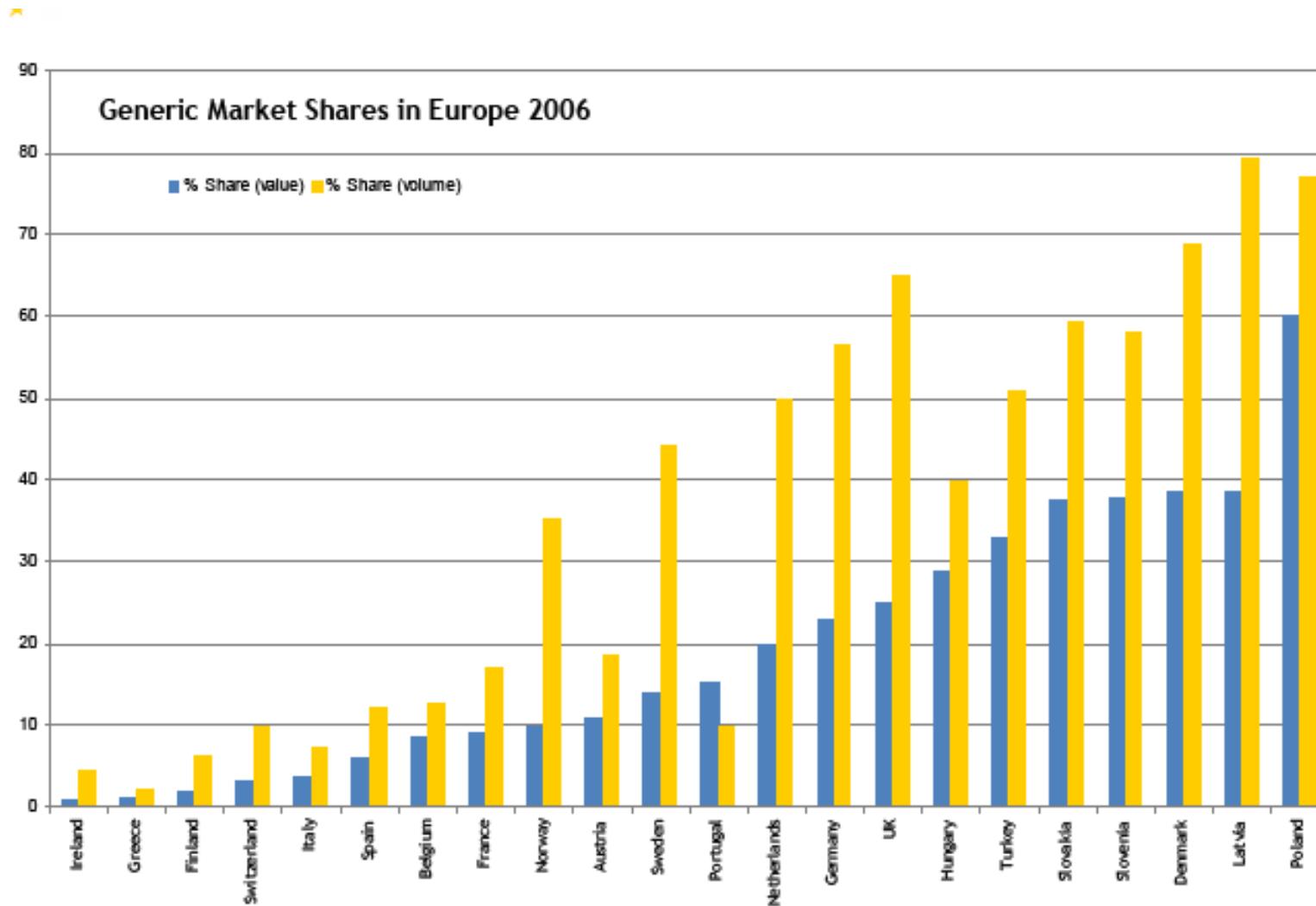
PRICE-DIFFERENCES FOR BASKET OF AVERAGE MEDICINES



DIFFERENCES IN NATIONAL WEALTH AND RESOURCES (GDP/CAPITA)



GENERICS ALLOW SIMILAR TREATMENTS AT LOWER PRICES



Source: National Association 2007
© EGA 2007

Source: European Generics Association

RISK SHARING AND CONDITIONAL P&R ALLOW FACILITATED ACCESS IN UNCLEAR SITUATIONS

Situation

- Complex situation due to:
 - § Potential strong benefits...
 - § ... but not yet prove, doubt about value
 - § ... and very high prices
- è Solution in a conditional agreement
 - § Limited time period
 - § Controlled number of patients/maximum costs
 - § Study setting
- è Comforts all parties
 - è Patients have an early use/access of medicine
 - è Control of budget for funding authorities, with certainty that knowledge on the value will soon be better known
 - è Early reward for innovation for companies

Increasing use

- UK – Velcade
- IT – Performance risk-sharing (Bayer)
- UK – MS
- BE – Conditional reimbursement
- NL – Conditional reimbursement in hospitals
- LT – Conditional reimbursement
- ...

IMPROVE EU-WIDE ACCESS TO ORPHAN DRUGS

SPECIFIC BOTTLENECKS DUE TO RARITY

Key bottlenecks

- Risky development of orphan drug
- Assessing uncertain clinical value
- Difficult pricing/reimbursement deals
- Limited awareness and skills

Potential Ways forward identified

- EC Regulation* + National incentives
- Early Dialogue
- Flow information on orphan drugs
- Bundle fragmented know-how
- Promote conditional pricing/reimbursement
- Monitor/study utilisation
- Standardised patient registers
- Network centers of expertise

NECESSARY STEPS TO GET A MEDICINE TO THE PATIENT INTO A SMALL NATIONAL MARKET



Tasks (costs)

- Market Autorisation
- Pricing decision
- Reimbursement dec.
- Marketing and sales
- Pharmacovigilance
- ...

- Design packs
- Translations
- Production of pills
- Pack batches
- Label batches
- ...

- Transport
- Stock
- Order processing
- Local distribution
(Dispensing)
- ...

Driving actor

- M.A.H. or his agent

- M.A.H. / manufacturer

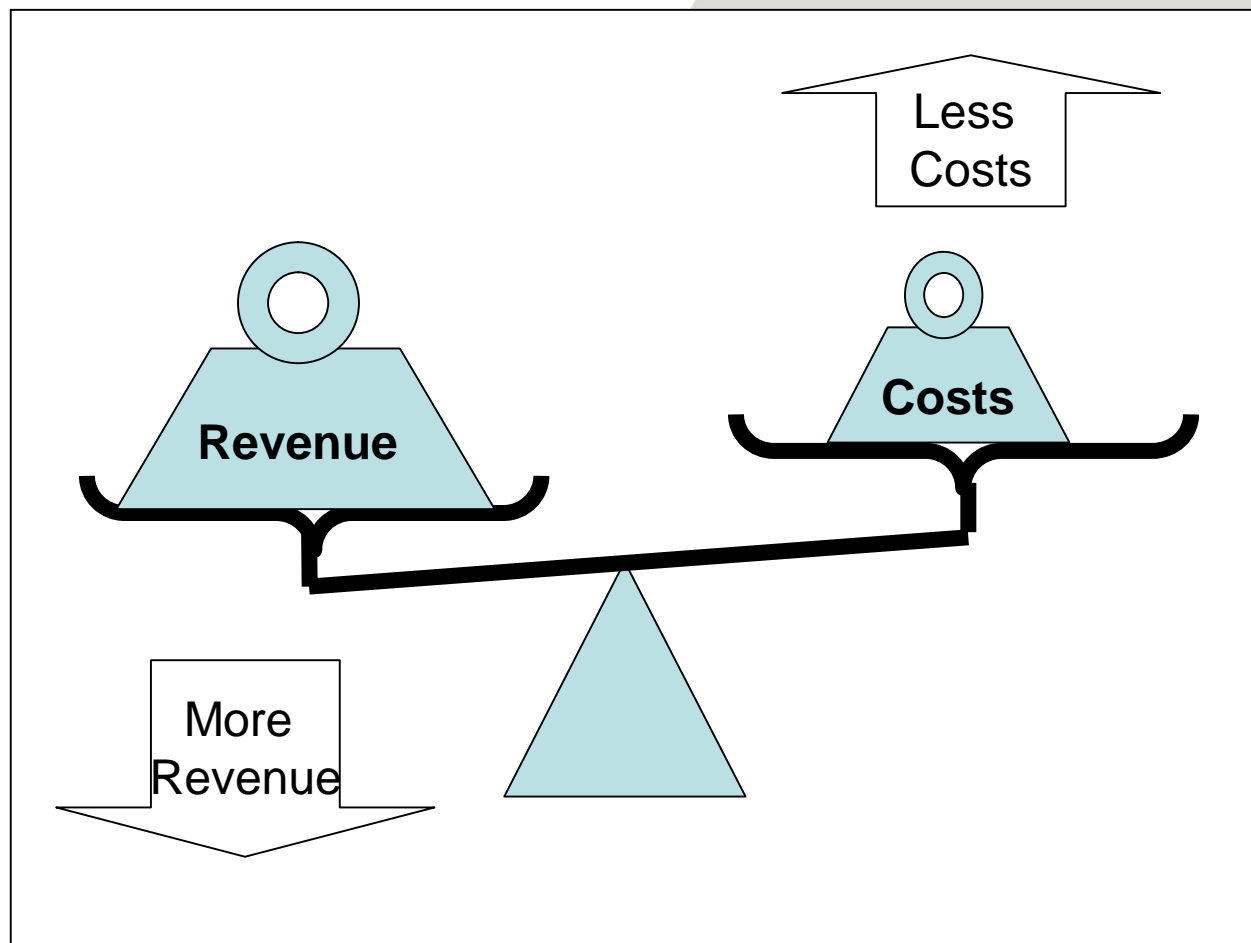
- Wholesaler
(/ Pharmacies)

Reward (revenue)

- Ex-factory price

- Ex-factory price

- Wholesale margin
(/ pharmacy margin)





THANK YOU

