

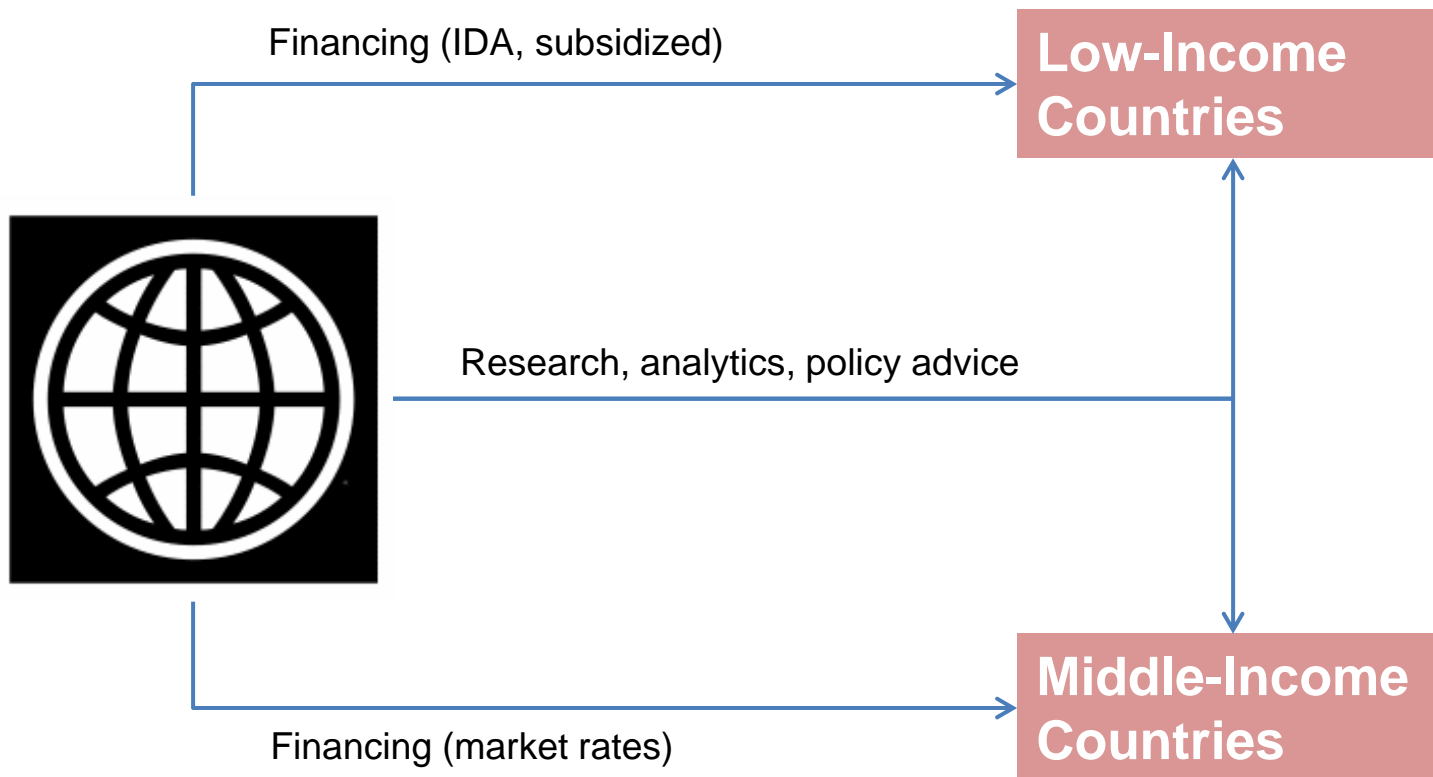
Pharmaceutical Pricing and Reimbursement – A Global Perspective

Andreas Seiter

The World Bank

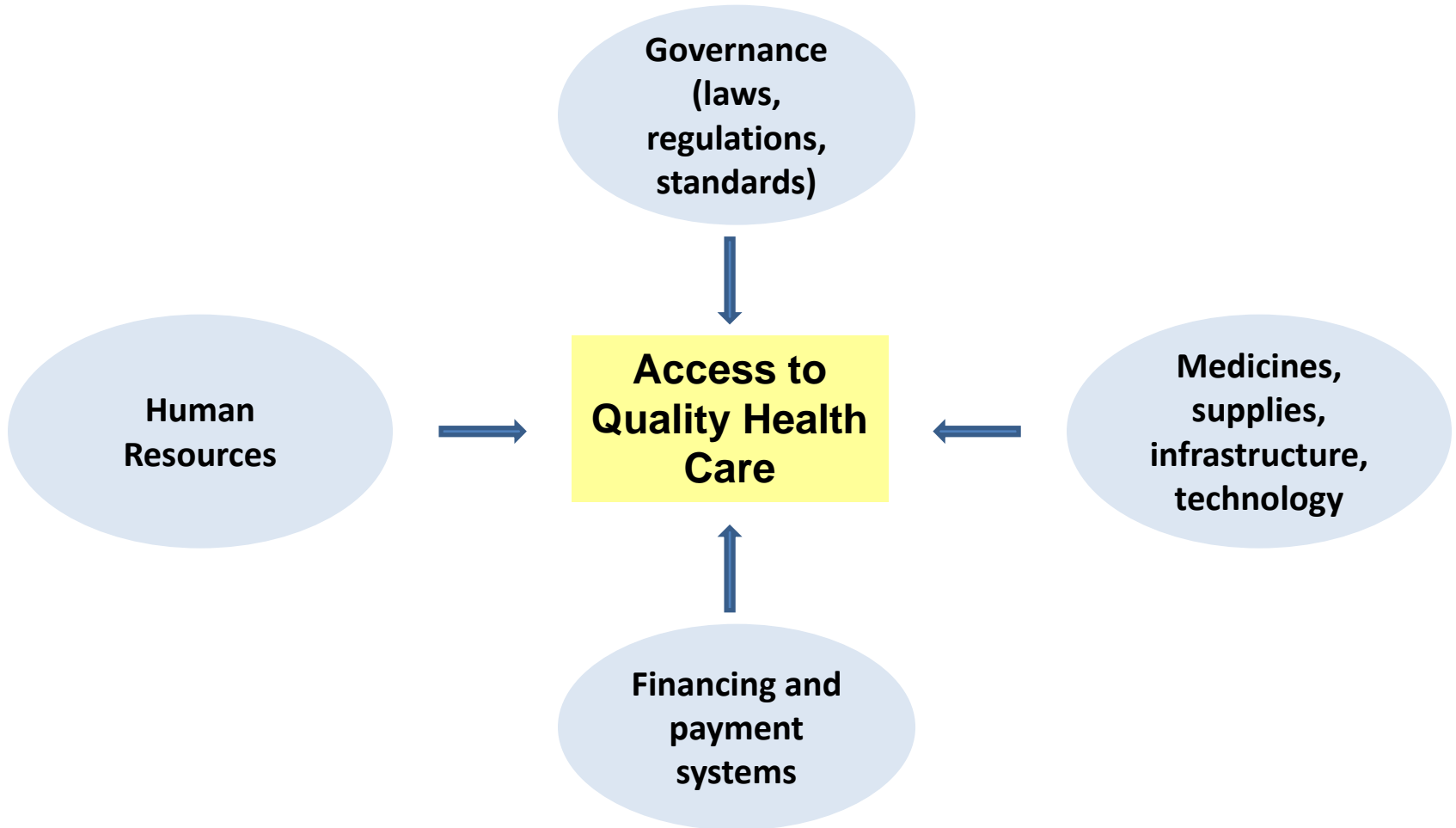
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The World Bank and its Clients



Overall goal: reduce poverty, increase equity

Health Systems Focus



Core Challenges for Policy Makers

Low income

- Availability
- Quality
- Affordability
- Adherence
- Lack of resources requires prioritization of life-saving treatments with high public health impact

Middle income

- Equitable access
- Rational use
- Perception of quality
- Financial protection
- Affordability of innovative treatments

Systemic Issues

Market failure

- Fragmented buyers
- Uninformed consumers
- Biased professionals
- Conflict between public health and private incentives

Weak governance and management

- Lack of accountability
- Outdated HR policies
- Fragmented decision making
- Corruption
- Lack of business skills
- Lack of technical skills
- Lack of data and transparency

Behavior of Unregulated Markets

- Providers maximize profit by targeting the affluent
- High need and weak bargaining position for consumers = low price elasticity of demand
- Strong branding efforts create consumer loyalty
- Many drugs will be unaffordable for poor people
- Market may sustain a lower cost segment with cheap generics targeting lower income groups

Historic Background Factors

- Public sector involvement in service delivery
- Segmented insurance or financing systems
- Self-dispensing doctors
- Size and quality of private sector in health
- Role of traditional medicine

Rationale for Price Regulation

- Protecting consumers (vulnerability in the case of illness)
- Staying within limited budget
- Getting more value/volume for the money
- Improving access for the poor
- Protecting domestic industry, stimulating R&D investment (?)
- **But price regulation alone is not sufficient to achieve any of these objectives!**

Pricing by Manufacturers

- Based on “willingness to pay”
- Considering competitive situation
- Trying to maximize “brand equity”
- For innovative drugs: global price band
- Differentiation between list price (public) and effective price (minus rebates, bonuses – usually confidential)

Pricing by Regulators

- Based on “objective” benchmark
 - Manufacturing costs? Profit?
 - Country of origin price?
 - Basket of reference countries?
 - Price of comparable products?
- Intention is to limit costs to consumer, public budget or insurance fund
- Often influenced by industrial policy considerations (examples Switzerland, Jordan)

Other Pricing Policy Elements

- Taxes, tariffs, administrative fees
- Distribution margins or flat fees
- Statutory rebates for public buyers
- Currency fluctuation adjustment
- Pay-back, claw-back and other contractual mechanisms that influence net payment

Risks of Regulated Markets

Depending on type of regulation

- Little incentive for price competition
- Reduced pressure for efficiency gains
- Isolation from global price trends
- Supplier focus may shift to
 - Polishing data used by regulators
 - Frontloading supply chains to boost volume
- Chronic stock-outs for less profitable products

Duality Pricing/Reimbursement

In countries with health insurance or publicly funded drug benefit plans:

- Reimbursement policy influences the market
- Price usually is one of the reimbursement criteria
- Reimbursement rules become an indirect tool for price regulation
 - “we only reimburse if you lower the price to x”
 - “we reimburse only the amount x - whatever your price is”

Standard Pricing Tools

- Reference pricing (innovator, generic)
- Reimbursement ceilings (internal referencing)
- Pooled purchasing/contracting

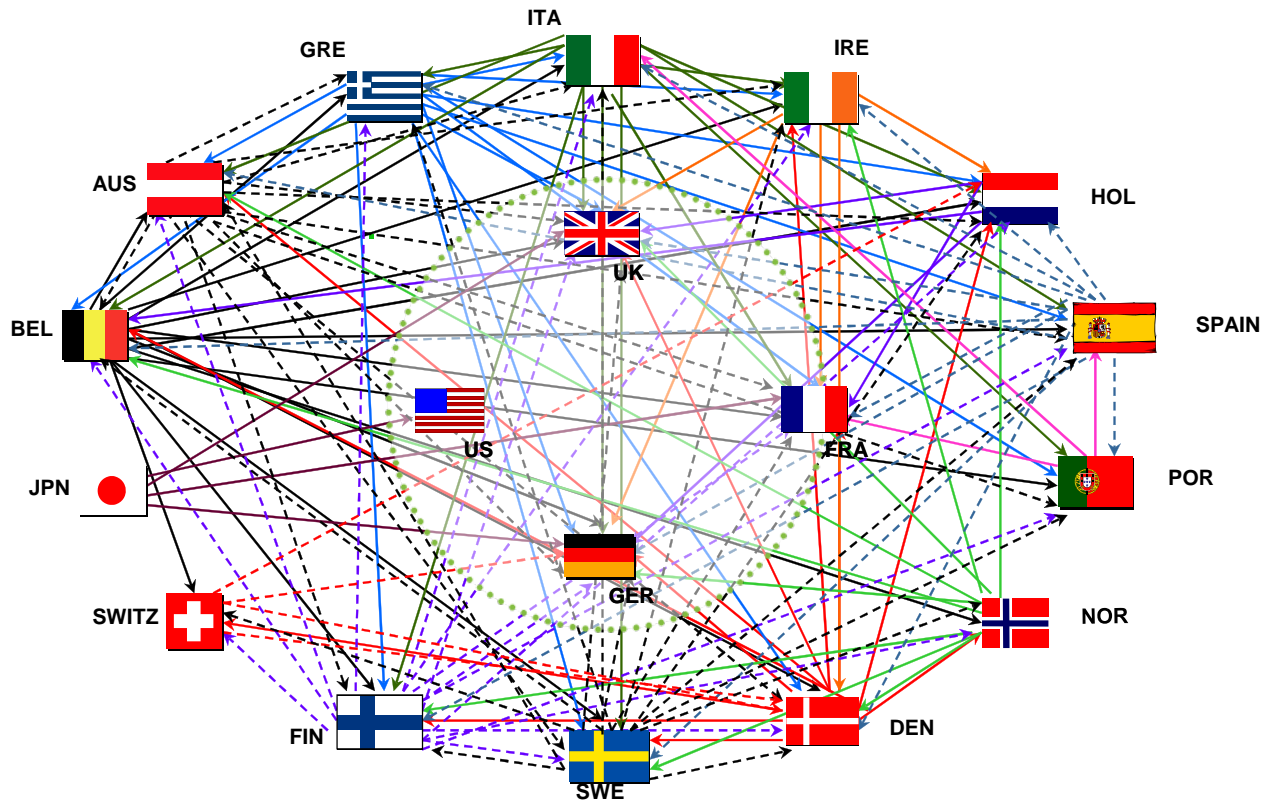
“Reference Pricing” – Two Meanings

- Setting a fixed or maximum price based on comparison with prices in other countries (external referencing)
- Setting a maximum reimbursement level within a health insurance formulary based on a low price, adequate and sufficient treatment option (reimbursement ceiling)

External Referencing

- Mostly done for newer, patented drugs
- Comparison based on a group of countries
- Lowest, mean, median or any other reference level can be chosen
- Price data obtained from industry, ministries or third party source (example OEBIG in Austria for EU countries)
- Different pricing systems and price components must be considered

External Referencing

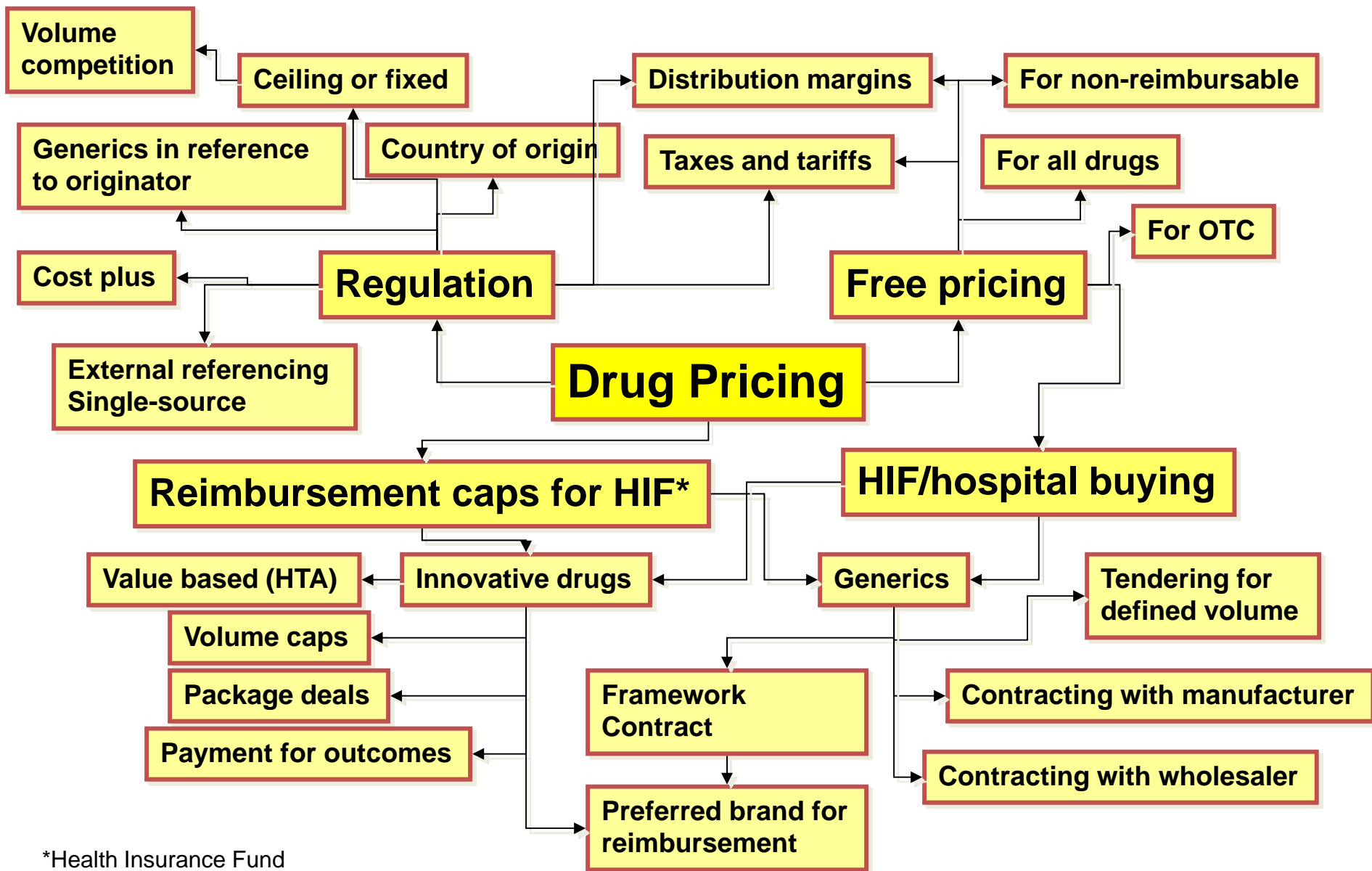


Self-limiting concept? What happens once all countries are referencing to each other?

Generics Pricing in Reference to Original

- In many countries, generics are priced at a certain percentage of the original
- Example: first generic 70%, next 10% less and so on until a low enough level is reached that serves as a price ceiling for all other generics entering the market

Drug Pricing “Mind Map”



*Health Insurance Fund

Reimbursement Ceilings (1)

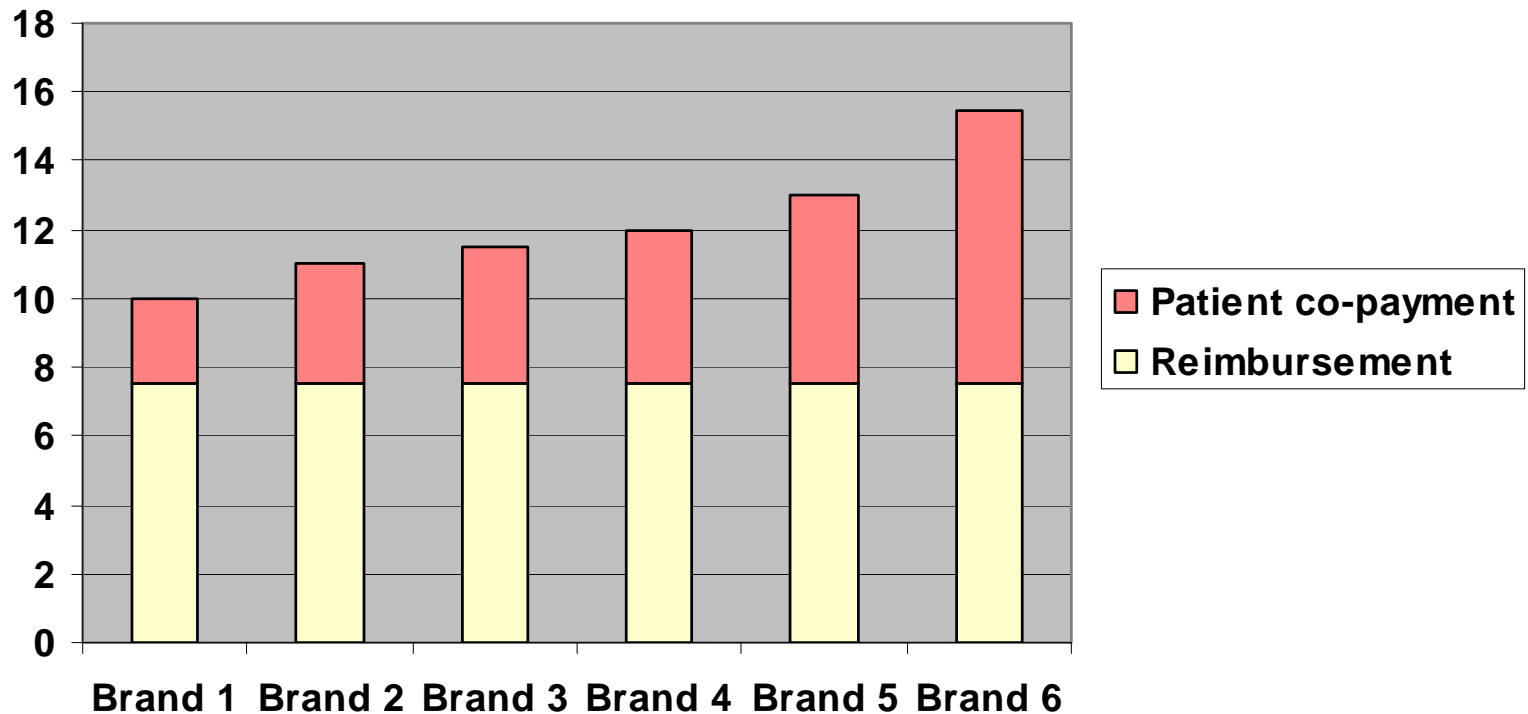
- = internal referencing
- Assuming quality of all alternatives is acceptable
- Lowest cost option defines maximum reimbursement
- Market price not affected, unless manufacturers lower prices in response to ceiling
- Patient pays the difference!

Reimbursement Ceilings (2)

- Grouping by molecule (example ranitidine)
- Grouping by therapeutic class (example: all H2-antagonists)
- Grouping classes together if clinical efficacy/safety profile is similar (example: H2-antagonists and proton pump inhibitors)
- Conflict with multinationals if patented drugs are included
- Patient pays the difference – depending on incentives and persuasion power of providers!

Standard Reimbursement Model

A set percentage of the lowest generic price (in this example 75%) is reimbursed; the patient pays the difference to the price of the specific brand - but is in many cases not aware that a cheaper option would be available!

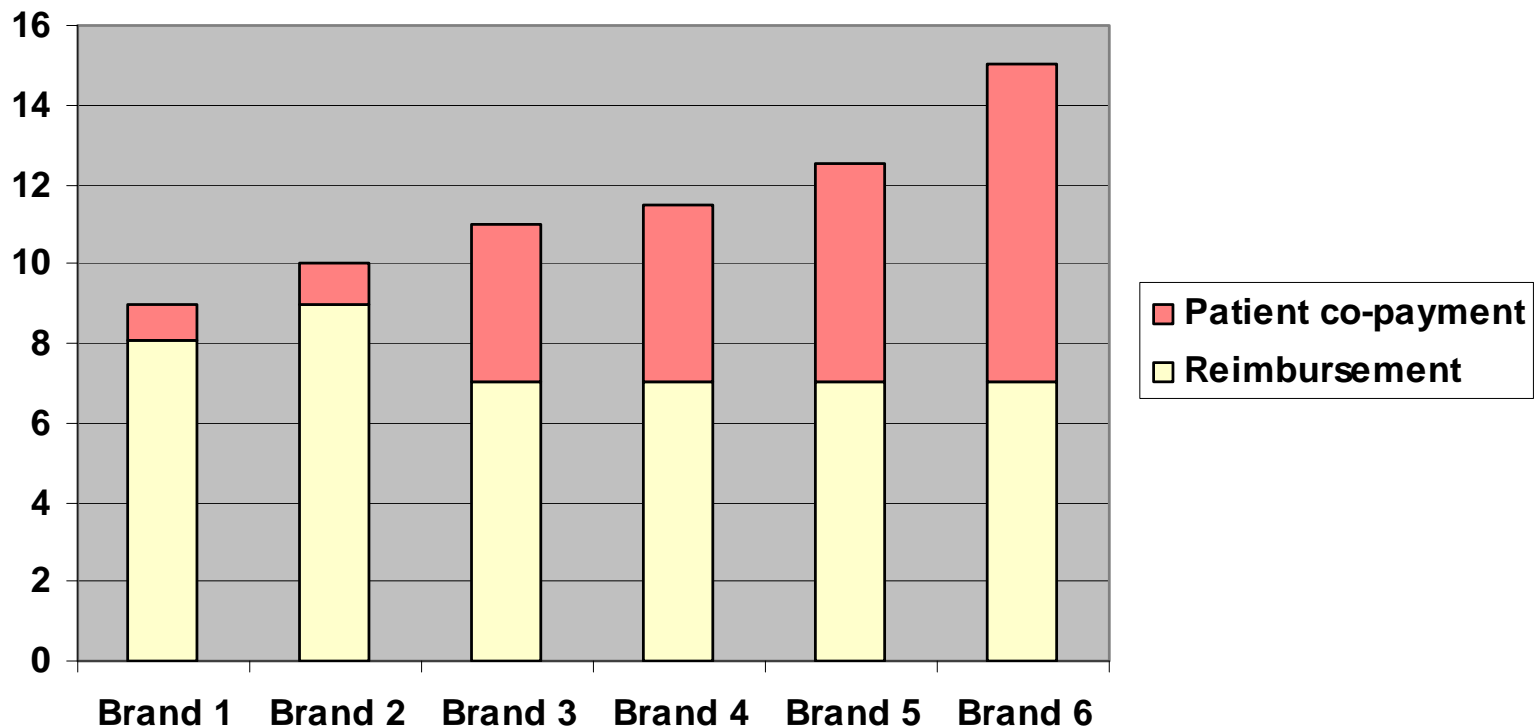


Unwanted Effects of Capped Reimbursement

- Fixed reimbursement rates eliminate incentive for price competition
- Generic manufacturers fight for volume instead
- Bonus offers for distributors who push certain brands instead of price cuts
- Winners are wholesalers and retailers, losers are payers and manufacturers

Using Reimbursement Policy to Create Competition Among Generics

In this example, the reimbursement authority invites bids from makers of a given generic. Bidders have to state the maximum volume they can supply. Winners 1 and 2 together can supply the whole market and get higher reimbursement than all others (90%). Brands 3-6 only get 70% of the price of Brand 2 as reimbursement, creating a significant commercial barrier for these brands. Their manufacturers can come back with a better offer in the next round.



From Pricing to Expenditure Management

- Price is only one component of cost
- Price x Volume = Total Cost
- Supplier induced demand creates major cost pressure

Financial stress due to innovation

- New live-saving treatments come at high costs
- Affordability is an issue even for high income countries
- Rational treatment or rationing treatment?
- Key challenges:
 - Maximizing leverage in negotiations with manufacturers
 - Managing patient expectations and political pressures

Four questions

How much do we need it?

How much can we afford to pay for it?

New, \$ 30,000 cancer treatment

How can we get the best deal?

Who is going to get it once we have it?

Perception bias

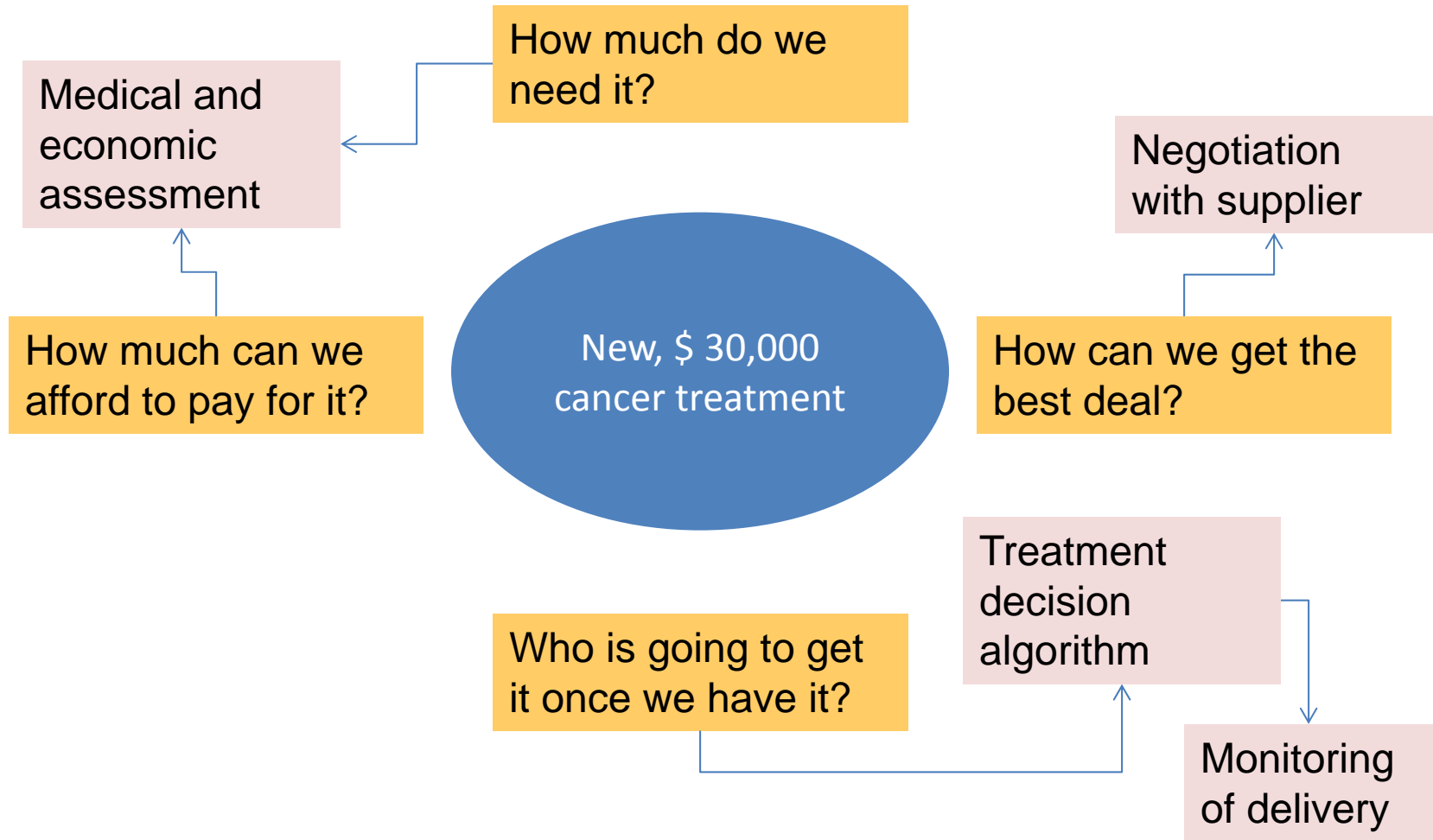
1000 children immunized

1 cancer patient's life
extended for 1 year

Who gets more publicity = lobbying power?

- Saying “no” is difficult
- “Yes but with tight restrictions” politically more viable

Decision steps



Medical and economic assessment

Publicly available data & analysis (example NICE)

Decisions made by other countries

Manufacturer provided data

Considering

- Health priorities
- Applicability of data
- Available funds
- Economic impact
- Subjective suffering
- Delivery capacity
- Other relevant factors

Rejection

or

Go-ahead for negotiations with supplier



Getting more value for money

- Pricing regulations and reference pricing schemes reduce suppliers' flexibility in pricing negotiations
- Budget ceiling with flexible volume usually better accepted
- Marginal costs of production low compared to price
- No template for deals – good preparation and negotiation skills are key to success
- Example for a result: fund pays for max. 100 treatments, supplier fulfills demand beyond 100 based on a defined application/selection process

Deal Making with Industry

Tenders for preferred position on reimbursement list	Low price in exchange for high market share
Pooled procurement	Volume rebates in cash or free goods
Volume ceiling	Company lowers price or provides free goods if amount sold exceeds limit
Package deals	Volume or cash rebate given for drug B in exchange for accepting price of drug A
Outcome based pricing	Payment conditional on treatment success

Contractual Arrangements with Industry

Manufacturer	Therapeutic area	Type of contract	Insurer/Partner
AstraZeneca	Gastro-intestinal Blood pressure	Rebate Rebate	German BKK German BKK
Eli Lilly	Anti-psychotics Diabetes	Rebate Rebate	9 AOKs, German BKK, TK Several insurers
GlaxoSmithKline	Respiratory diseases	Added-value	Under negotiation
Janssen-Cilag	Anti-psychotics	Rebate	AOK Rheinland- Hamburg, TK
Novartis	Osteoporosis Transplant rejection drugs Ophthalmic drugs	Risk-share Risk-share Cost capping	DAK, Barmer DAK Under negotiation
Novo Nordisk	Diabetes	Rebate	German BKK
Pfizer	Cholesterol-lowering drugs	Rebate	German BKK
Sanofi-Adventis	Diabetes	Rebate	Several insurers

Source: Financial Times Germany

Personalized Case Management

- A single patient can represent an investment of several 10,000 US\$ per year
- Most new treatments target NCDs = long time patients
- Success and relative cost-effectiveness depend on
 - Ensuring adequate patient selection
 - Monitoring compliance and outcomes
 - Discontinuing treatment in case of non-compliance, side effects or lack of success

Key success factors

