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Pharmaceutical Pricing and Reimbursement – A Global Perspective

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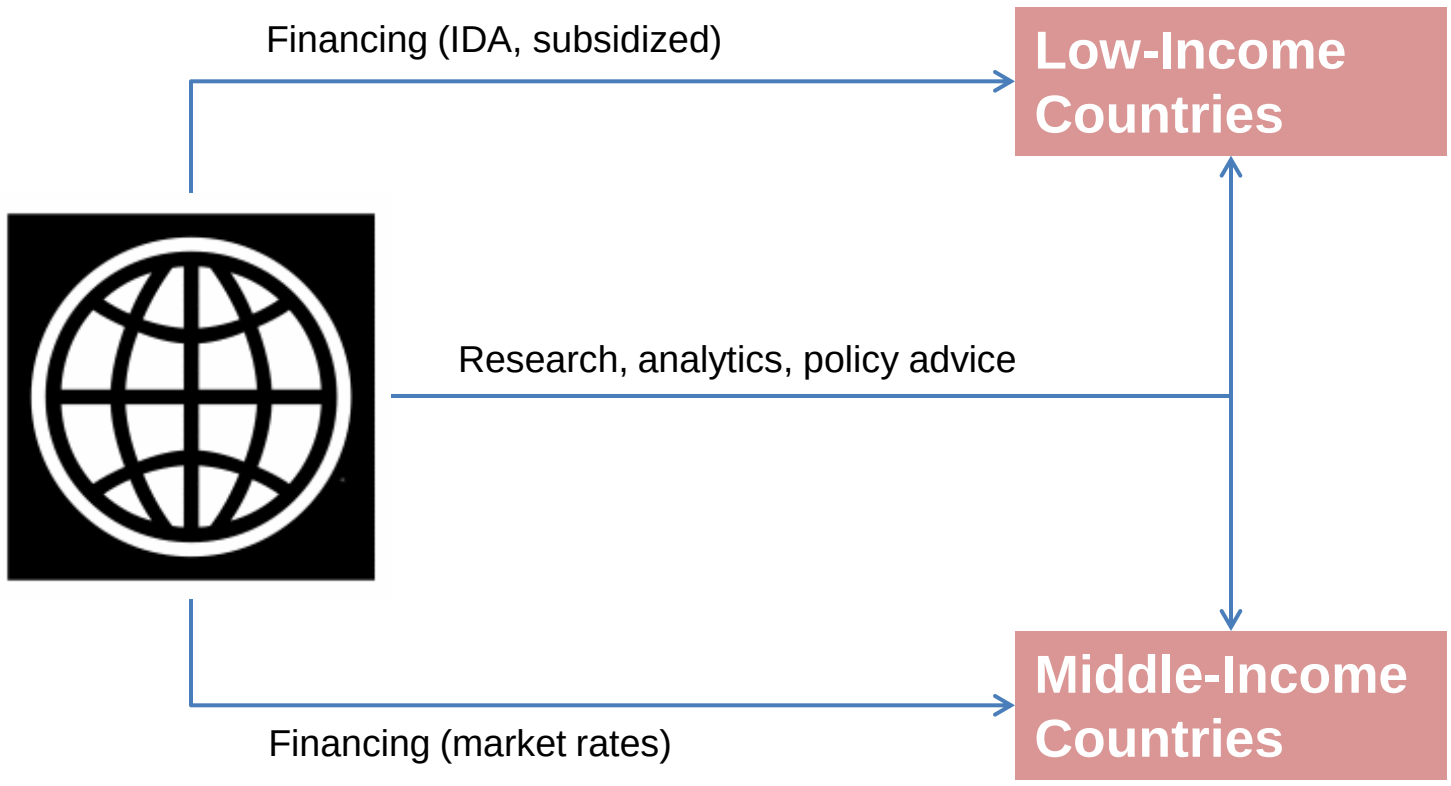
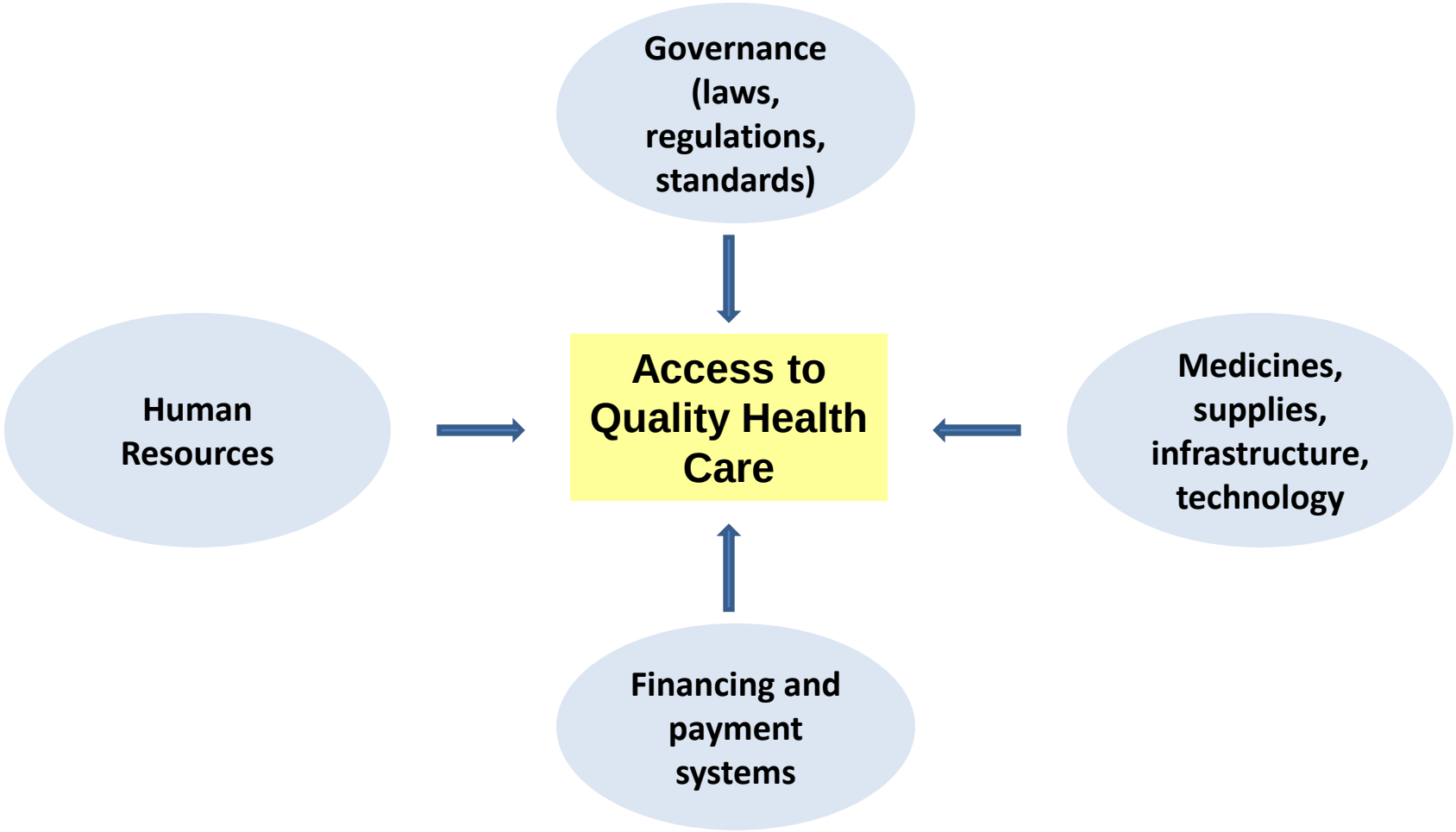
The World Bank and its Clients



Overall goal: reduce poverty, increase equity

Health Systems Focus



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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

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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- Outdated HR policies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

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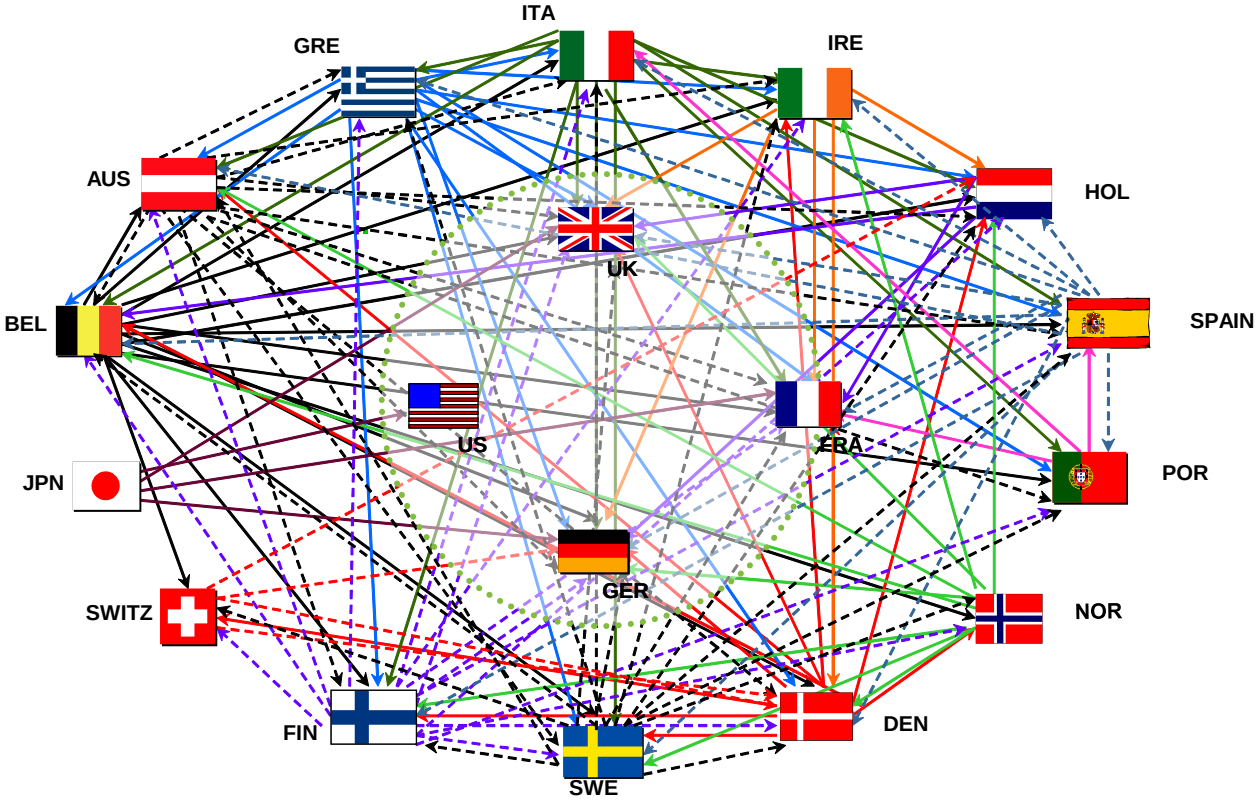
External Referencing

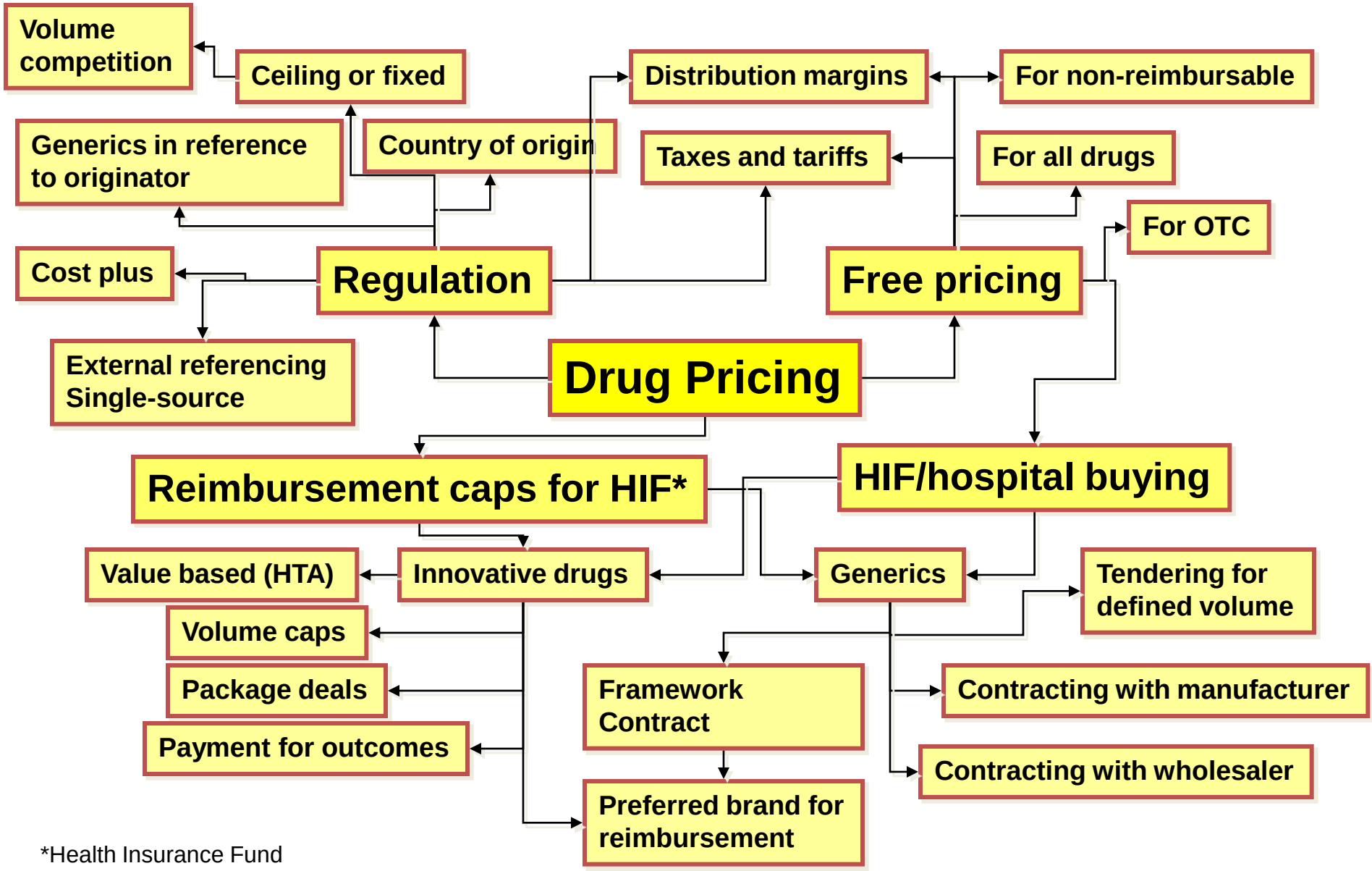


Self-limiting concept? What happens once all countries are referencing to each other?

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!

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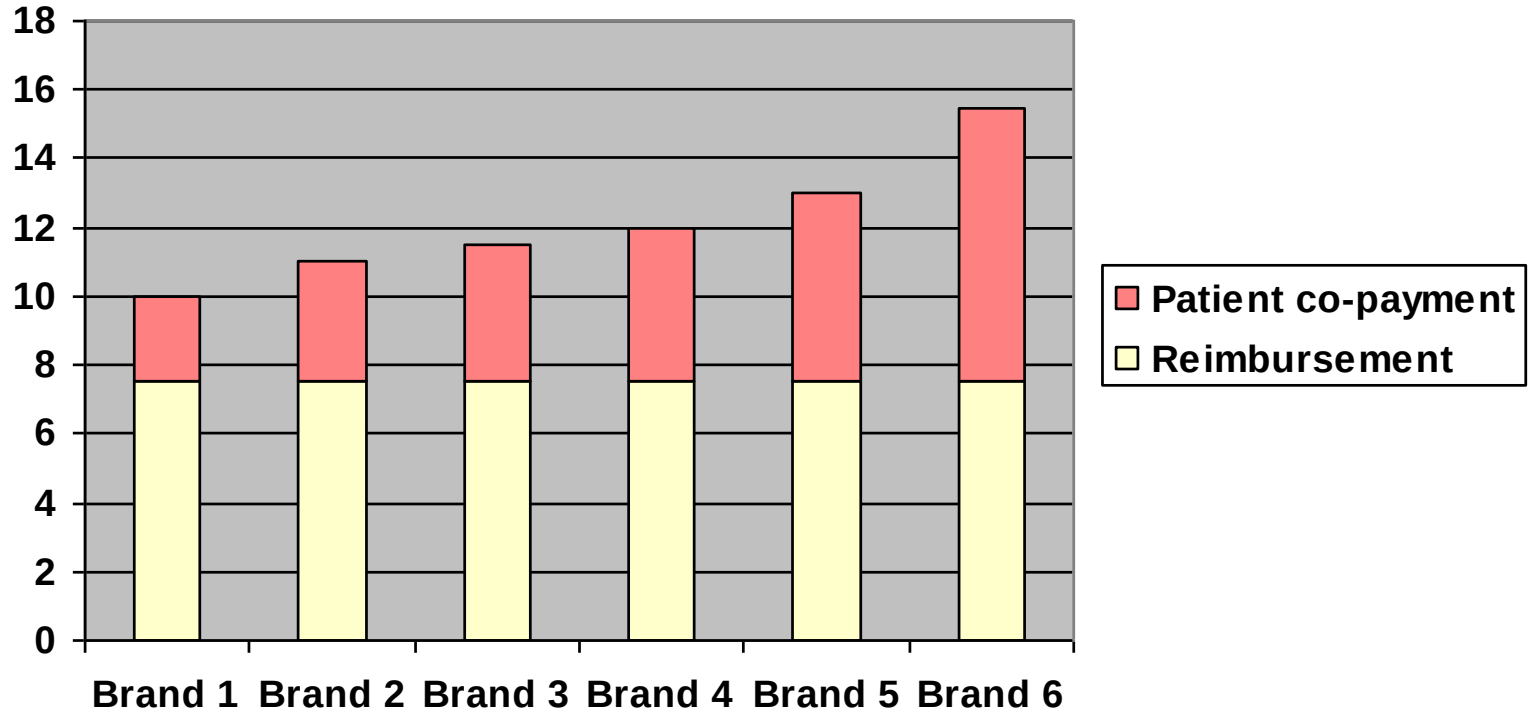
Standard Reimbursement Model

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

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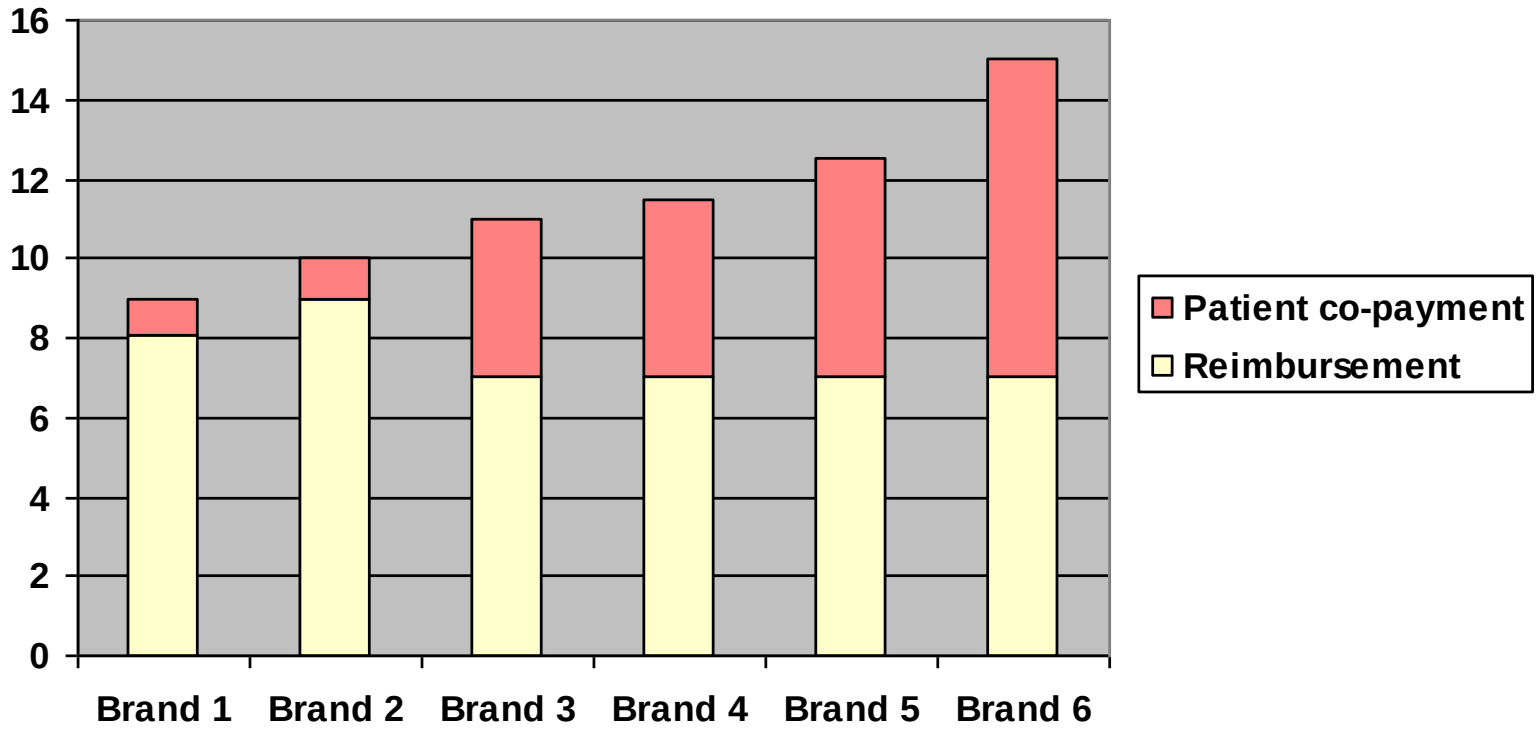
Using Reimbursement Policy to Create Competition Among Generics

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

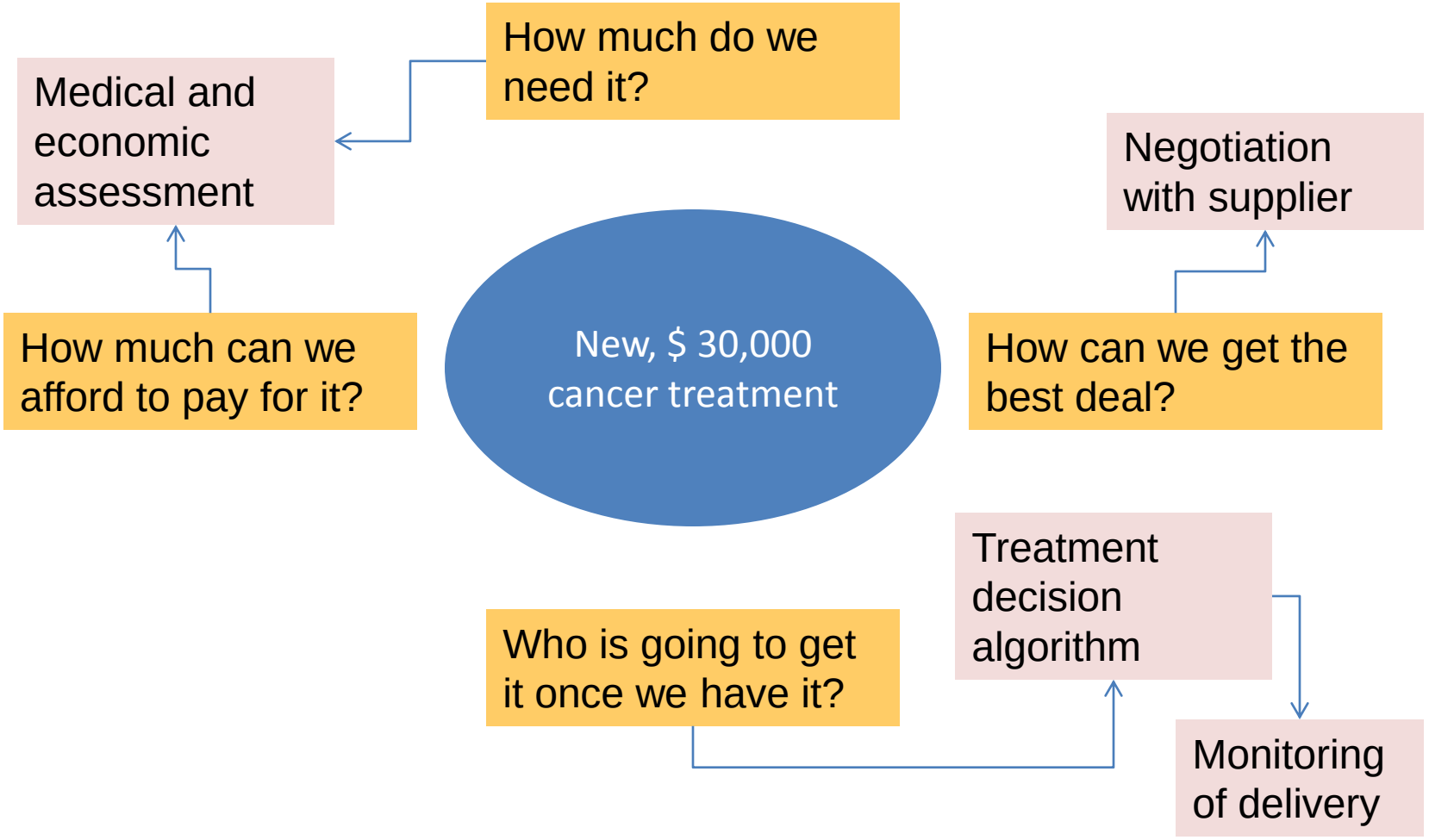
1000 children immunized

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



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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 of lack of success

Key success factors