Pharmaceutical Pricing and Reimbursement – A Global Perspective

Andreas Seiter
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The World Bank and its Clients

- Low-Income Countries
  - Financing (IDA, subsidized)
  - Research, analytics, policy advice

- Middle-Income Countries
  - Financing (market rates)

Overall goal: reduce poverty, increase equity
Health Systems Focus

Access to Quality Health Care

- Governance (laws, regulations, standards)
- Human Resources
- Financing and payment systems
- Medicines, supplies, infrastructure, technology
### 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- Outdated HR policies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
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”

Drug Pricing

- Volume competition
- Ceiling or fixed
- Generics in reference to originator
- Country of origin
- Cost plus
- External referencing Single-source

Regulation

- Cost plus
- Generics in reference to originator
- Country of origin
- Taxes and tariffs

Distribution margins

- For non-reimbursable
- For all drugs
- For OTC

Free pricing

- Health Insurance Fund (HIF)
- Value based (HTA)
- Innovative drugs
- Generics

Reimbursement caps for HIF*

- Volume caps
- Package deals
- Payment for outcomes

HIF/hospital buying

- Tendering for defined volume
- Contracting with manufacturer
- Contracting with wholesaler

Preferred brand for reimbursement

- Framework Contract

- Payment for outcomes
- Innovative drugs
- Volume caps

*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!
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
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

How much do we need it?

New, $30,000 cancer treatment

How much can we afford to pay for it?

Negotiation with supplier

How can we get the best deal?

Treatment decision algorithm

Who is going to get it once we have it?

Monitoring of delivery
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

<table>
<thead>
<tr>
<th>Deal Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tenders for preferred position</td>
<td>Low price in exchange for high market share</td>
</tr>
<tr>
<td>on reimbursement list</td>
<td></td>
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<tr>
<td>Pooled procurement</td>
<td>Volume rebates in cash or free goods</td>
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<tr>
<td>Volume ceiling</td>
<td>Company lowers price or provides free goods if amount sold exceeds limit</td>
</tr>
<tr>
<td>Package deals</td>
<td>Volume or cash rebate given for drug B in exchange for accepting price of drug A</td>
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<tr>
<td>Outcome based pricing</td>
<td>Payment conditional on treatment success</td>
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</tbody>
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## Contractual Arrangements with Industry

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

- Benefit manager has negotiation mandate
- Business and negotiation skills
- Good preparation (evidence, demand, funds available)
- Affordable access to innovation
- Monitoring of utilization and outcomes
- Understanding economic rationale of manufacturer
- Restricted and managed access