Pharmaceutical Pricing – Policy Options

Andreas Seiter
The World Bank
June 2008
Basic Definitions

- Manufacturer price – COGS* plus profit margin
- Regulated price – set as price ceiling or fixed price based on a regulatory decision
- Market price – what actually is paid by the buyer in a transaction

* Cost of Goods Sold
Drug Price Components

- Large variations in share of factors – retail and distribution can absorb >90% in extreme cases
- Discounts/rebates can apply at any level
- Cost components are raw material, GM&A*, R&D, marketing costs, bonus goods, financing costs, costs for kickbacks and bribes, shipping costs, costs for testing / quality assurance, regulatory costs and profit margins for all levels

*General Management & Administration
Cost Elements that Influence Price

- R&D, manufacturing, raw materials
- Licensing
- Tariffs
- Taxes
- Insurance
- Shipping
- Wholesale margin
- Retail margin
- Marketing
Who Sets Prices for Drugs?

- Manufacturer
- Agent, wholesaler
- Regulator
- Market/Buyer
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 market price (in many cases 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

- Frequently considering interests of domestic industry; in some cases industrial policy aspect has been dominant (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
Market Pricing

- Tendering
- Price negotiations for buyer pools
- Discounts and bonuses (free goods) lower effective price
- Individual consumer has very little power versus “provider cartel”
- Market can function only if demand is pooled
Behavior of Unregulated Pharmaceutical 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 and OTC drugs targeting the poor

Assumption in this example: COGS = 40
Risks of Regulated Pharmaceutical Markets

Depending on type of regulation

- Less incentive for price competition
- Less 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
Overarching Issue - Governance

- Lack of transparency for non-experts makes pharmaceutical sector vulnerable for corrupt practices.
- Governance issues can affect regulated and unregulated markets equally although the patterns are different.
Kickbacks, leaks and schemes

- Manufacturer
- Wholesaler
- Retailer
- Patient
- Sales rep
- Regulator

- Kickbacks
- Collusion
- Bribes
- Theft, Diversion
- Favors, kickbacks
- Counterfeits

Free goods

"Bonus"
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)
- Regulation/market synergies
“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.
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 still pays the difference – consider 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.
Additional Measures to Support “Preferred Brand” Strategy

- Rigid enforcement of GMP regulation
- Information campaign for doctors and patients; “advertising” for generic quality in general
- Contractual obligation or incentives for doctors to prescribe preferred brands
- Margin neutrality and obligation to stock preferred brands for pharmacists
From Pricing to Expenditure Management

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

- Active Purchasing
- Consumer Empowerment
- Reimbursement
- Financing
- Retail Incentives
- Rational Prescribing
- Stringent Regulatory Enforcement
- Feedback and Control Mechanisms
# Deal Making with Industry

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

---
Country Examples

- Germany
- France
- Australia
- UK
- Austria
Germany

- Free pricing, drug prices relatively high
- Central commission for reimbursement
- Independent HTA institute IQWiG established, currently defining its methodology
- Reimbursement ceilings at lower third of price band; three different groupings: INN, chemical group and therapeutically equivalent drugs; groups include patented “me too” drugs
- Co-payments (10%, min 5 €/max 10 €); substitution, flat retail margin
- No co-payment for generics that are priced 30% below reimbursement ceiling – about 13000 specialties already
- Bonus goods for pharmacists illegal
## Germany – 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 Blood pressure</td>
<td>Rebate Rebate</td>
<td>German BKK German BKK</td>
</tr>
<tr>
<td>Eli Lilly</td>
<td>Anti-psychotics Diabetes</td>
<td>Rebate Rebate</td>
<td>9 AOKs, German BKK, TK Several insurers</td>
</tr>
<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 Ophthalmic drugs</td>
<td>Risk-share Risk-share Cost capping</td>
<td>DAK, Barmer DAK Under negotiation</td>
</tr>
<tr>
<td>Novo Nordisk</td>
<td>Diabetes</td>
<td>Rebate</td>
<td>German BKK</td>
</tr>
<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>
</tbody>
</table>
France

- Positive list with different reimbursement levels (100%, 65%, 35%) for serious versus mild conditions
- Separate assessment of therapeutic and economic value defines price and reimbursement rate
- Re-assessment of drugs for positive list initially after three years, then every five years
- Volume limits, price cuts if volume exceeds limit (contracts with industry)
- Reimbursement ceilings for a limited list of generic drugs
- Substitution rights for pharmacist, financial incentive to substitute
- Monitoring of physicians, no effective sanctions
Australia

- Single-payer system Medicare PBS
- Central commissions for benefits assessment and for economic assessment, strict criteria
- Annual price negotiations, generic price ceilings, ceilings for comparable drugs
- Indication limits for reimbursement, pre-approval for certain drugs
- Co-payments with safety net provision, substitution right for pharmacist
UK

- NHS contracts define which drugs can be prescribed (and are fully reimbursed)
- NICE – evaluation of new drugs provides guidance for NHS
- Profit based pricing (PPRS) with claw-backs, not very transparent for outsiders
- Pharmacy margins also adjusted based on profitability
- Generics reimbursed at average market price levels
- Flat dispensing fee for dispensing doctors
- UK £6.65 flat charge for prescriptions but several exemption categories and cap provision (pre-paid certificate for a quarter or a year)
- Pharmacy chains allowed
- Significant changes to pricing/reimbursement system expected based on an Office of Fair Trade Report from 2007
Austria

- Health insurance system similar to Germany
- Traffic-light classification of drugs
  - Red: new drugs, special permission needed (time limited)
  - Yellow: drugs with benefits for special groups; some with, some without special permission (dark/light yellow)
  - Green: reimbursed with no limits
- Price ceilings based on EU average
- After patent expiry 30% off original price
  - - 25% for first generic
  - - 15% for second generic
  - - 10% for third generic, then no more regulated price cuts
- Tendering possible if not enough generic competition
- Monitoring of prescribing patterns, potential penalties for doctors: overall cost increase within target corridor
Conclusions

Drug prices should be managed as one element of a comprehensive drug policy package rather than viewed in isolation.
Source for Further Analysis

EU PPRI Project (Pharmaceutical Pricing and Reimbursement Information)

See http://ppri.oebig.at