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
- Hidden in this chart are marketing costs including bonus goods, financing costs, costs for kickbacks and bribes, shipping costs, costs for testing and quality assurance, regulatory costs and profit margins for all levels
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

- Usually considering viability of domestic industry; sometimes industrial policy aspect is dominant (Switzerland, Jordan)
Market Pricing

- Tendering
- Price negotiations for buyer pools
- Discounts and bonuses (free goods) lower effective price
- Individual consumer has no power versus “provider cartel”
- Market functions well only if demand is pooled
Duality
Pricing/Reimbursement

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

- Reimbursement policy has a strong influence on the market
- Price usually is one of the reimbursement criteria
- Reimbursement becomes an indirect tool for price regulation
Behavior of Unregulated Pharmaceutical Markets

- Providers maximize profit by targeting the affluent
- Consumers are in a weak bargaining position
- Strong branding efforts to build consumer loyalty
- Many drugs will be unaffordable for poor people
- Market may give rise to a low-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
- Prices may lag global 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
- Kickbacks
- Collusion
- Bribes
- Free goods
- Collusion
- Regulator
- Theft, Diversion
- Sales rep
- Favors, kickbacks
- Sales
- Wholesaler
- “Bonus”
- Counterfeits
- Retailer
- Patient
- "?

The diagram illustrates the flow of kickbacks, leaks, and schemes involving various parties such as manufacturers, regulators, sales representatives, wholesalers, retailers, and patients. It highlights the connections between kickbacks, bribes, fraud, and theft in a network of illegal activities within the procurement and distribution of goods.
Objectives of Pricing Policy

- Reasonable prices for innovative drugs
- Price competition in the generics market
- More efficient spending of public or insurance funds for medicines (more volume / value for the money)
- Patient protection against overpayment
- Sufficient supply on the market
Reimbursement “Mind Map”

- Economic value
  - Generics: GMP, bioequivalence
  - Medical need
- Price/cost
- Manageability

Criteria
- Reference to decision of others
- Transparency
  - Decision tools
- Commission
  - Expert assessment
  - Application review

Selection process
- Management
- Adaptability
  - Generics/equivalents
  - Preferred brand for reimbursement
- Cost control
  - Level of co-payment
  - Utilization control
    - Monitoring
      - Feedback, training
      - Incentives, sanctions
  - Package Deals
    - Negotiated price
      - Volume caps
        - Payment for outcomes
          - Pre-approval
  - IT system, simulation
    - Reimbursement ceiling
“Reference Pricing” – Two Meanings

- Setting a market (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
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!
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
Creating Synergies Between Regulation and Market

- Regulated maximum prices protect consumers who pay out of pocket
- Institutional buyers use their purchasing power to create price competition
- The tool: lower or no co-payment for the cheaper brand(s)
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!
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
De-politicizing Decision Making

- The pharmaceutical sector is dominated by strong financial interests
- Major manufacturers have more resources, access to technology and skills than governments
- Clear, transparent rules and procedures help reduce political interference
- Consultation processes need to be structured and clearly de-coupled from decision making
- Neutral supervision (non-medical experts, educated civil society members) useful as well
- Professional communication is a must – resources for communication need to be planned from the outset