Pharmaceuticals in a Global Environment

The Story of Heartburn

The Purple Pill

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Prilosec, 20 mg

As needed for acid reflux

Anne Johnosn

MD Signature

"Brand Name" Drug

"Over-The Counter" Drug

Nexium®
(esomeprazole magnesium)

Today's Purple Pill

"Me-Too" Drug

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Omeprazole, 20 mg

As needed for acid reflux

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MD Signature

"Generic" Drug

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Nexium, 40 mg

As needed for acid reflux

R. Jimenez z

MD Signature

"Brand Name" Drug

GLOBAL ISSUES

Price Discrimination—
The same commodity is sold at different prices to different consumers.

Product Selection—
Which drugs are developed and marketed

The pharmaceutical industry consists of three components:

1. Research & Development
2. Marketing
3. Manufacturing and Distribution

Research & Development

- Global investment of $58 billion in 2000
- Recent estimates for a new drug: $800M to $1.7B
  Takes 5+ years
- Patent protection for 20 years;
  Chemical modification to extend patent life
- FDA says only 1/3 of new drugs applications are truly innovative, the remainder is for little or no improvement on existing therapies
- Generics after patent protection expires
  Some drugs become over-the-counter
- Companies looking for “blockbuster” drugs ,but they are rare

Marketing

- Prescribed drugs are selected by the physician; the patient is passive in product selection
- Advertising in medical journals and pharmaceutical reps (Not unbiased information)
- Direct to consumer (DTC)-encouraging patients to tell their physician they want to try a product-shown to lead to unnecessary use of new and expensive drugs, but also a decrease in number of patients not receiving appropriate drugs
- Third party intermediaries are also part of the decision-making process (shift from fee-for-service)

Manufacturing and Distribution

- There is a great imbalance among regions of the world in production, sales and consumption.
- Pharmaceutical R&D occurs primarily in the wealthy industrialized countries of North America, Europe and Japan, but is shifting to China.
- Manufacturing occurs in many countries. They are then exported or produced throughout the world
- The poorest countries do not produce Western pharmaceuticals (although traditional medicines are produced in every country).
- In the last decade, a few lower-income countries, including India, South Africa and Brazil have become important producers.
- They produce copies of existing drugs and sell them to poor countries whose populations and governments cannot afford to purchase products from industrialized countries

HOW ARE DRUG PRICES DETERMINED?

- Supply-side factors such as costs
  - High fixed costs for R&D and marketing;
  - Low marginal cost for manufacturing and distribution
  - Marginal costs determine price in a competitive market, but fixed costs do not
  - Pharma's position is that fixed costs must be part of the final product-this is the essential point of controversy
- Demand factors
  - Drug attributes
  - Consumption decision parties-the physician, the patient, the pharmacist and the insurer

EXPLORING PRICE DISCRIMINATION

- Brand Name Product / Generic Substitute / Over-the-Counter
- Profits rise when price is set according to each consumer group's willingness to pay and its demand pattern
- Price paid is a function of purchasing power
- Pharmaceutical companies strive to sustain demand for higher priced (usually brand name) drugs
- "Me-Too" Drugs

An example:

- Drug prices on branded pharmaceuticals are as much as 25-40% higher in the U.S. than in most other parts of the world, certainly more than most developed countries.
- Generic drugs in the United States are generally cheaper than in the rest of the world due to the large number of U.S. firms that rush to take advantage of expired patents.
- So, the U.S. system is not necessarily more expensive; the pricing system is just different. Americans pay more initially while drugs are under patent protection, but prices fall below the rest of the world once generics are introduced.

WHY ARE DRUG PRICES SO HIGH?

- Over the last 30 years, control of drug development, supply and pricing decisions is under the private sector
- Corporate interests lie in maximizing profits and growth, not in identifying and filling health needs
- Maximizing profit means getting rid of non-competitive products, regardless of the health needs; many of these are for malaria, sleeping sickness and other third-world diseases
- In most Western countries, impact is offset by health insurance systems, government subsidies or development incentives (Orphan Drug Act in U.S.)
- Developing countries are often too poor to shield patients from the brunt of industry production and pricing strategies

Cost Containment Strategies

Public Sector

- Federal Level: Food and Drug Administration (FDA)
- State-Level
  - Purchasing Pools
  - Single agency among 12 states to compare cost and efficacy of drugs to guide formularies
  - Reimportation – buying drugs from countries that received lower pricing structure

Cost Containment Strategies

Private Sector

- Manufacturer discounts - negotiating wholesale price
- Substitution of generic and therapeutic
- Formularies – limits range of drugs physicians can prescribe to one or two within a therapeutic class
- Tiers – more formulary choices but higher out-of-pocket cost for patient
- "Step Therapy" - a treatment course where the most cost-effective solution is tried first, and more expensive therapies are explored only when that treatment fails.
- Drug Utilization Review

WHY DO DRUG PRICES VARY ACROSS COUNTRIES?

- Purchasing Power
- The first determinant of the price people in a country will pay for drugs is the country's income.
- Patients in wealthy countries are less sensitive to price and more likely to have insurance to shield them from the cost
- For both reasons, patients in wealthy countries have less price sensitivity, less willingness to substitute less expensive drugs, and less willing to forego use of drugs

ACCESS TO APPROPRIATE DRUGS IN DEVELOPING COUNTRIES

Two Key Challenges

1. Reliance on imported pharmaceuticals that are priced at world levels
   - Price discrimination
   - Poor countries often lack the infrastructure of a drug-purchasing agent that represents *all* of a country's potential consumers
   - World Trade Organization agreements:
     Trade-Related Aspects Of Intellectual Property Rights (TRIPS) -- Response to losses from patent infringement
     Each member county commits to provide a basic level of patent protection

2. Lack of congruence between the health needs of the country and the drugs that are available or imported

- Low rate of return for R&D investment in diseases of developing country
- One is more likely to see drugs introduced in developing countries if the drug also has a market in developed countries.

World Health Organization Drug Action Program

- To ensure availability of “essential” drugs
- Publishes a list of 319 drugs considered essential for managing the most prevalent illnesses in developing countries

Two relatively poor countries, Brazil and India, are developing substantial pharmaceutical industries.

- Initially, concentrated on older drugs at low cost for domestic consumption (often had lost patent protection)
- Enabled them to offer many of WHO essential drugs
- With other countries, appealed to UN to suspend international patents for public health emergency (AIDS)
- Indian firms are starting to produce their own patented medicines
- Brazil, like many developing countries, is able to formulate, package and market pharmaceutical specialties
- However, they failed to develop advanced chemistry infrastructure