

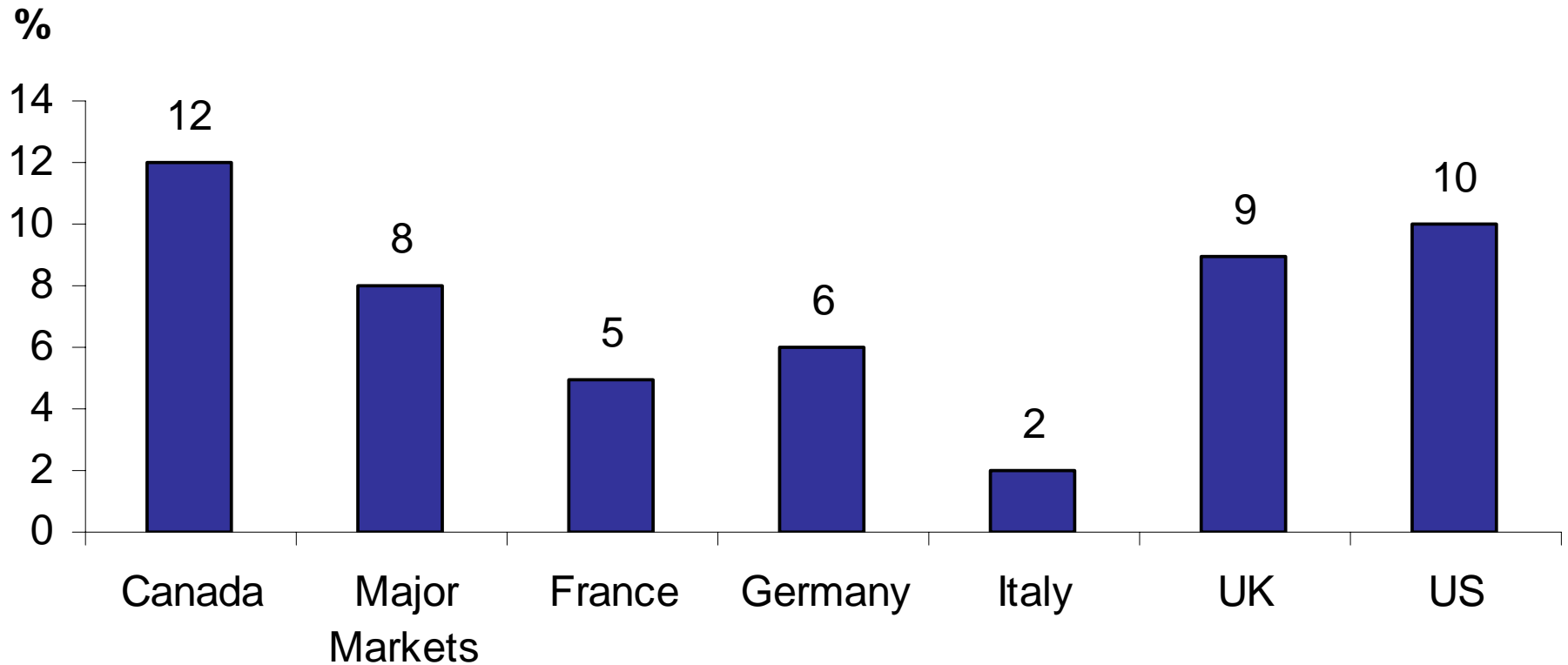
# Pharmaceutical Financing/Reimbursement Policy in Turkey

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# Growth in Pharmaceutical Sales for 2003

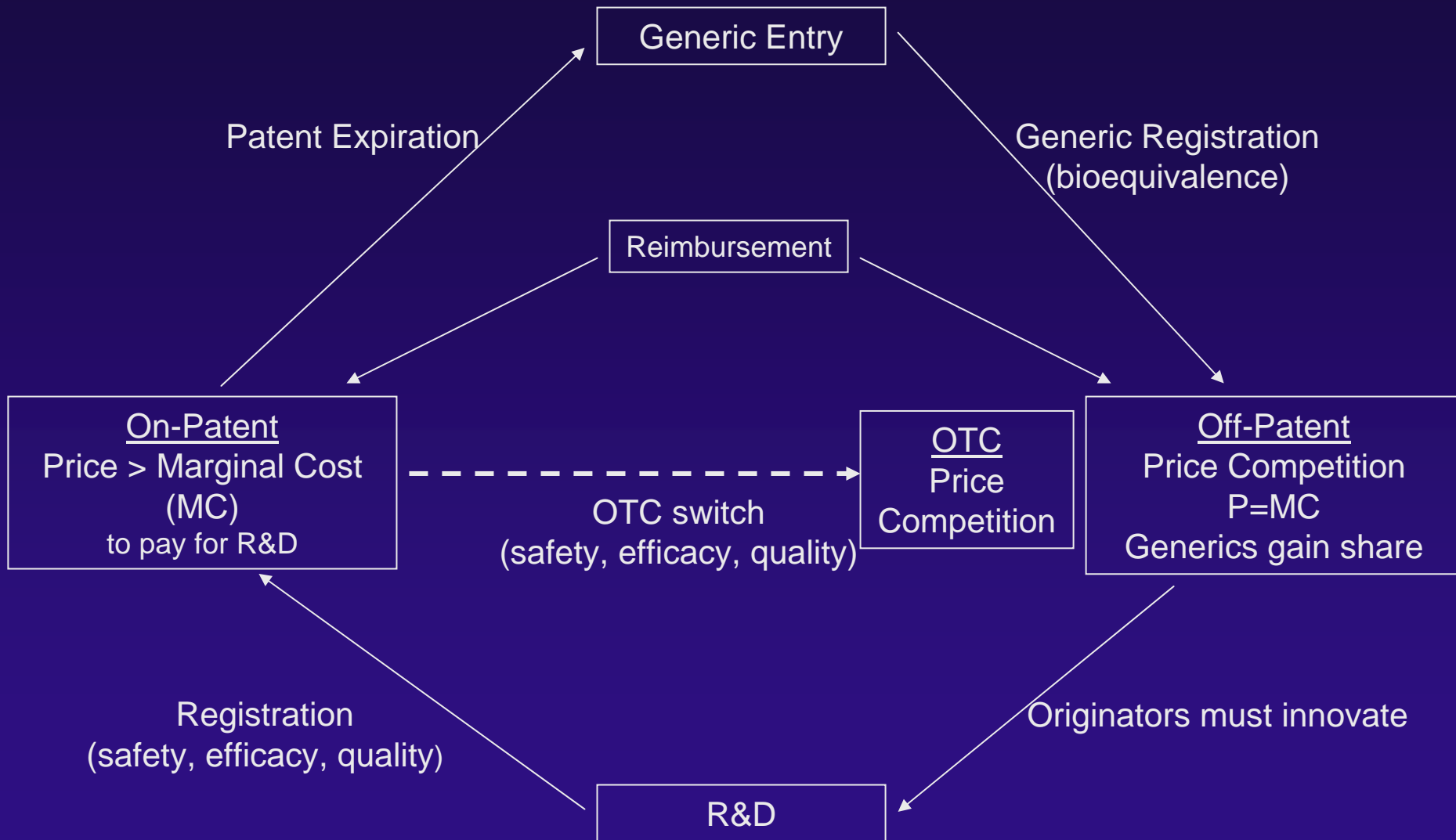


The Major Markets category represents more than two thirds of the world market and is made up of 13 countries: Argentina, Australia, Brazil, Canada, France, Germany, Italy, Japan, Mexico, New Zealand, Spain, the UK and the US (IMS Health, 2003)

## Pharmaceutical spending is growing in most countries: per capita and share of health spending

- ◆ Innovation => New products and new formulations
- ◆ Increase in volume of prescriptions
- ◆ “Upgrading” from old to new products  
=> increasing price per prescription
- ◆ Pure price increases (for a given drug) are small in most countries
  
- ◆ Achieving maximum savings on off-patent compounds is key to free up budget resources to pay for new products

# Dynamic Competition in Pharmaceutical Markets



# Pricing for On-Patent Brands: Two Basic Approaches: 1. External Referencing

## 1. External referencing to same product in other countries

– Italy; Canada; Spain; Netherlands; Japan; Turkey etc.

◆ Main rationale is objectivity and transparency

◆ Potential disadvantages:

– Not based on the country-specific value of the drug

– May undermine appropriate cross-national price differences

- Differential pricing, based on countries' per capita income, is the appropriate way to share the global cost of R&D

- External referencing, if used, should apply between countries at similar income levels

# Pricing for On-Patent Brands:

## 2. Internal Benchmarking

### 2. Internal benchmarking to competitor products in same country

- France, Belgium, Japan etc.

- ◆ Markups for

- Improvement in efficacy, safety, convenience

- Higher price for local production?

- Price/volume trade-offs?

- ◆ A possible risk is lack of transparency, long negotiations

- ◆ But this approach is potentially more consistent with value to consumers and cost-effectiveness

# Using Cost-Effectiveness in Reimbursement or Pricing Decisions

- A new drug is cost-effective relative to comparator drug if the incremental cost, relative to the incremental efficacy, is less than the payer's threshold:

$$\frac{(P_n - P_0)}{(E_n - E_0)} \leq K \text{ (maximum acceptable cost per unit effect)}$$

Equivalently:  $P_n \leq P_0 + K (E_n - E_0)$

$P_n$  = price of new drug

$P_0$  = price of comparator drug

$E_n - E_0$  = incremental efficacy/safety e.g. quality adjusted life years QALYs

- Other direct and indirect costs could be included in P
- Other measures of effectiveness can be used: life expectancy gained etc.
- K = maximum acceptable cost per QALY (e.g \$30,000) is country-specific

# Pricing Based Internal Benchmarking Should be Consistent with Reimbursement Based on Cost-effectiveness

Solving for  $P^{\max}$  = maximum price at which the new drug is cost-effective:

$$P^{\max} = P_0 + K (E_n - E_0)$$

$P_0$  = price of internal benchmark drug

$(E_n - E_0)$  = incremental efficacy/safety

- This C-E formula for  $P^{\max}$  is the similar to the formula for pricing based on internal benchmarking with mark-up for innovation
- Pricing decisions based on internal benchmark + markup should yield prices that are consistent with reimbursement decisions based on cost-effectiveness

# Pricing based on Internal Benchmarking and C-E Reimbursement Decisions Can Use Similar Data

- ◆ Internal benchmarking and CE evaluations can use similar data on prices of comparator products, outcomes, cost offsets etc.
  - Some data are country-specific (costs, threshold willingness-to-pay  $K$ )
  - Some data are from international trials (efficacy, safety)
- ◆ Note: At  $P^{\max}$ , the seller would capture all the social value
- ◆ In price negotiations, payers may negotiate to reflect other factors volume offsets, domestic production etc.

# Maximizing Savings in the Generics Sector After Patent Expiry: Necessary Conditions

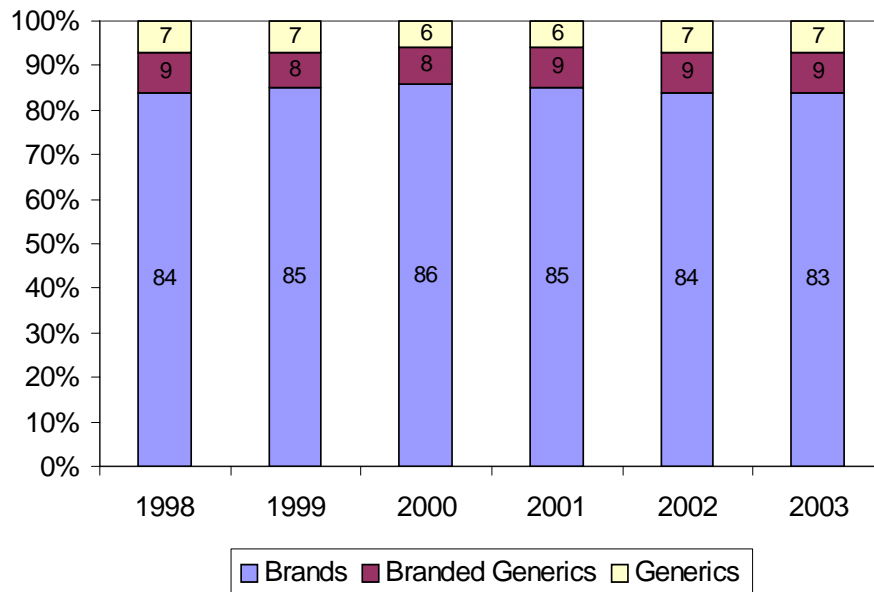
- ◆ Registration: generics must show bioequivalence to originator drug + quality
  - => Patients and physicians are willing to substitute generics
- ◆ Pharmacists are authorized to substitute (unless physician requires the brand)
- ◆ Generic prices are unregulated
- ◆ Reimbursement is based on a reference price (RP) for the molecule
  - RP is based on a low-priced product (usually generic) in the molecule
  - Patient pays the excess if prefer a product with  $P > RP$
- ◆ Pharmacy is paid a fixed dispensing fee + can profit if  $P < RP$ 
  - => Generics compete on price to gain market share
- ◆ Payers revise RP down over time, based on actual prices paid by pharmacies (including discounts)
  - => Payers and consumers capture the savings from generic competition

# International Experience Confirms These Conditions are Necessary for Low Priced Generics

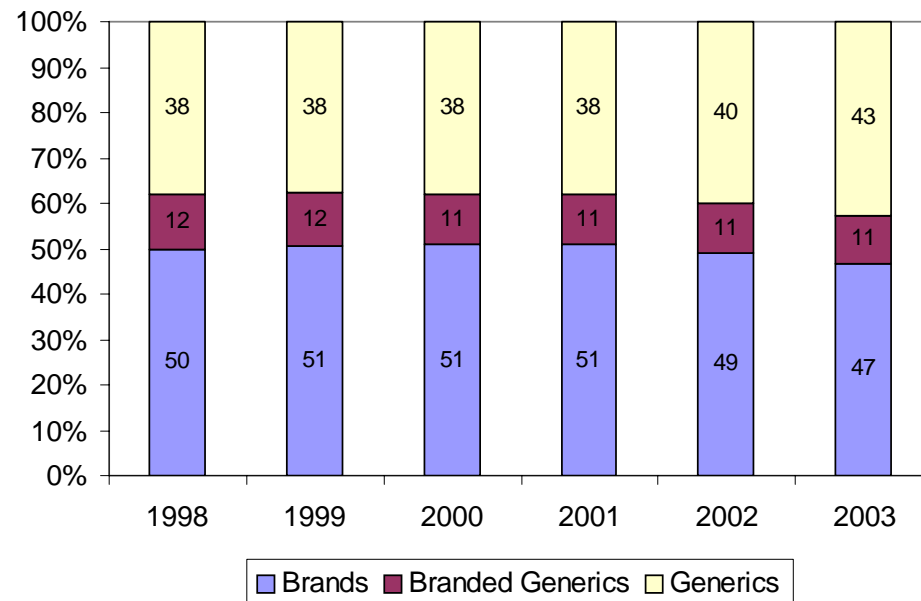
- ◆ US: Generics gain 80% of volume once patent expires
  - Most generics are unbranded and compete on price => very low prices
- ◆ UK: NHS captures savings from generic competition through “clawback” (reduced pharmacy reimbursement, to reflect average generic and PI discounts)
- ◆ Germany: large branded, generic share, relatively high generic prices
  - Pharmacies traditionally not authorized to substitute + paid a regressive margin (until 2003)
  - => Generics compete on brand more than price
- ◆ France: small generic share, mostly branded
  - Pharmacies traditionally not authorized to substitute + paid a margin
  - 2003 Incentives for generic prescribing

# US: Unbranded Generics Are 43% of Prescriptions, only 7% of Sales

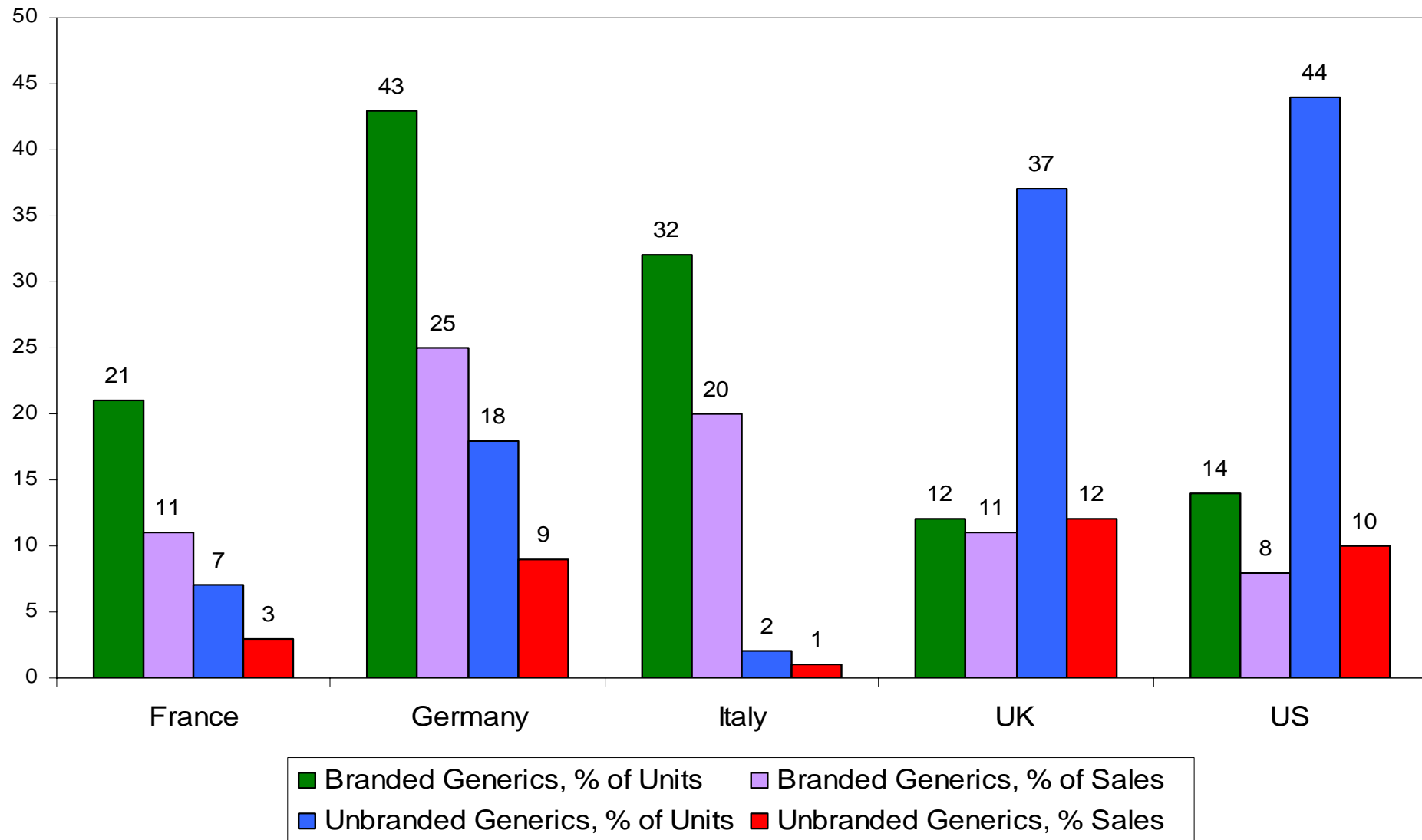
% Dollars



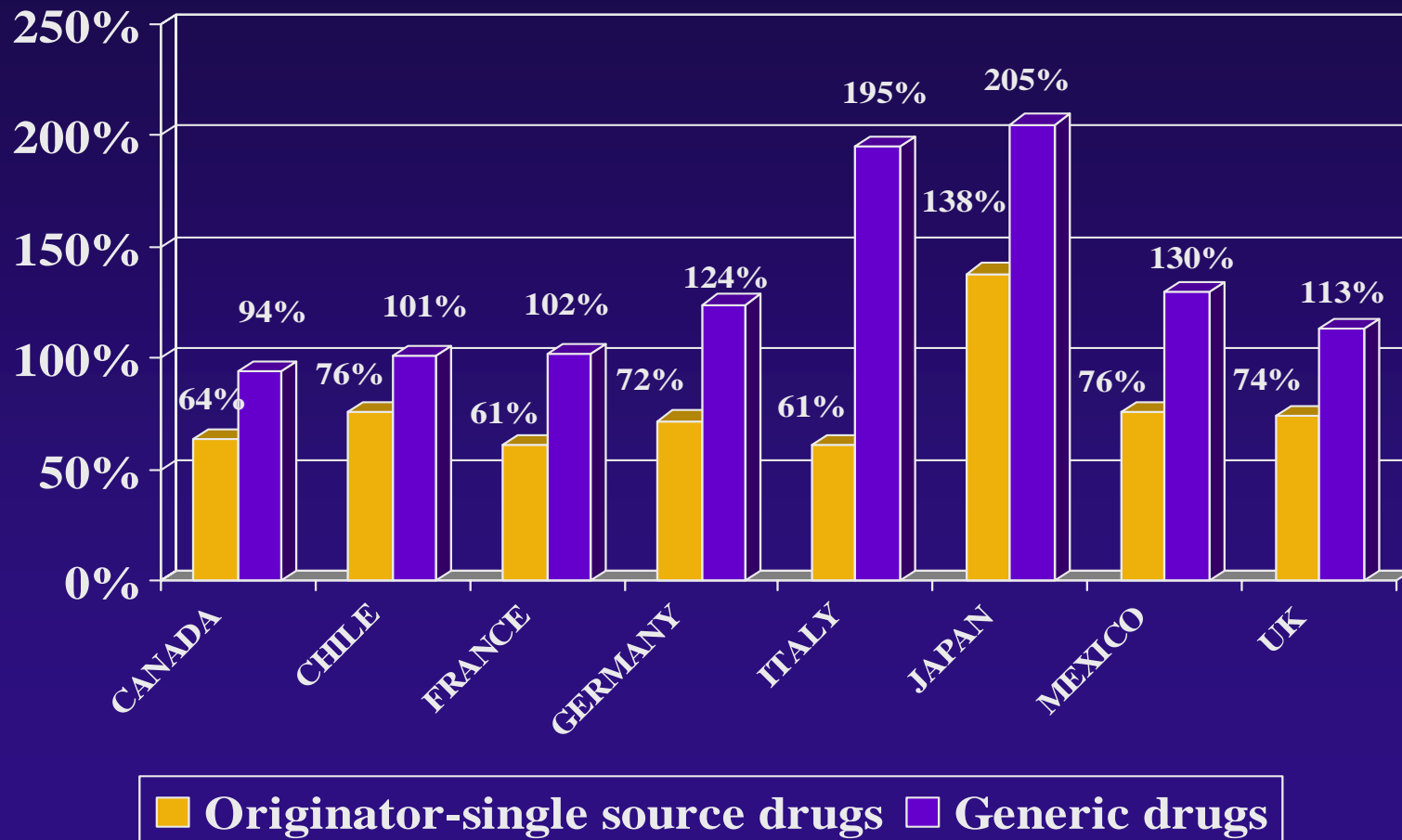
% Total Prescriptions Dispensed



# Generics: Branded vs. Unbranded Shares of Units and Sales (1999 IMS data)



# Price Indexes for On-Patent Originator Versus Generic Drugs (US Market Basket, 1999)



Note: United States equals 100%. Source: Danzon and Furukawa, *Health Affairs*, 2003

# Generic Referencing for Off-patent Compounds Should Not Be Confused with Therapeutic Referencing for On-patent Compounds

## Generic RP (off-patent only)

Italy

Portugal

Sweden

Denmark

Spain

UK

US

Canada

France

+ others

## Therapeutic + Generic RP

Germany (2004 some on-patent  
products added)

Netherlands

New Zealand

Australia (some ATCs)

British Columbia (some ATCs)

# Generic Referencing for Off-patent Compounds is not the same as Therapeutic Referencing for On-patent Compounds (continued)

- ◆ Generic RP for off-patent compounds is widely accepted
  - bioequivalent generics are accepted as good substitutes
  - applies only to off-patent compounds => little effect on R&D
  - can generate savings for payers and consumers
- ◆ Therapeutic RP applies same reimbursement to different compounds
  - compounds may differ in efficacy, safety
  - undermines effective patent protection, if on-patent compounds are grouped with off-patent compounds
  - undermines incentives for R&D
  - at most minor savings to payers

# Therapeutic Referencing Does Not Stimulate Dynamic Price Competition

- ◆ When a reference price (RP) is established as the maximum reimbursement for a group of products, some higher-price products may cut their price to the RP, to maintain market share
- ◆ But no firm has an incentive to price below the RP
  - i.e. the RP becomes a floor
  - ⇒ no dynamic price competition over time
- ◆ 1993 Netherlands adopted therapeutic reference pricing
- ◆ 1996 Netherlands added price controls based on external referencing (Belgium, UK, France, Germany)
  - Therapeutic RP was ineffective at reducing prices
- ◆ For evidence on RP in Germany, the Netherlands and New Zealand, see Danzon and Ketcham, *NBER*, 2003.

# Over-the-Counter (OTC) Drugs: Traditional Criteria for OTC Status

- ◆ Characteristics of Indication
  - Patients can easily self-diagnosis and treat
  - Self-limiting with time
  - Minimal involvement with healthcare professionals
  - No need for ancillary measures (e.g. diagnostics, blood test)
- ◆ Drug characteristics
  - Convenient, simple dosing regimen / dosage form
  - Obvious effects
  - Prompt onset
  - Safe and well tolerated
- ◆ Cough and cold remedies, vitamins, pain medicines, etc.

# Increasingly, some prescription drugs are switched to OTC status: UK, US and others

- ◆ Motivated partly by payers' budget pressures
- ◆ Patients are now more aware, more involved
- ◆ Applies to drugs with long history of safety
  - e.g. anti-ulcerants, antihistamines
- ◆ Switched drugs may have to demonstrate safety and efficacy under self-medication in new clinical trials
- ◆ OTCs are generally not reimbursed
- ◆ OTC switching saves money for payers IF patients face significant co-payment on more expensive prescription alternatives

# Patient co-payments

- ◆ Co-payments on pharmaceuticals are increasing in many countries
- ◆ Co-insurance percent of the price is more effective than fixed co-payment per prescription
- ◆ Co-payments vary by type of drug
  - Lower % for essential drugs
  - Higher % for convenience/minor medications
- ◆ Recent delisting from reimbursement of OTCs and other minor medications has reduced total drug expenditures in Germany, Italy
- ◆ Ideally, patient co-payments should be capped, based on income
  - Germany, Japan have income-related limits
  - Other countries have exclusions for low-income population

# Conclusions

- ◆ Many countries, like Turkey, are seeking to get maximum value for their pharmaceutical spending
- ◆ Promising strategies include:
  - On-patent pricing: Internal benchmarking + markups for innovation; consistent with cost-effectiveness review for reimbursement
  - Maximizing savings from generics for off-patent compounds
  - OTC switching + non-reimbursement for drugs with proven safety for self-medication
  - Co-payments adjusted for indication and patient status