

Medicine price regulation – the South African experience

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Republic of South Africa

Overview

Healthcare challenges facing South Africa in 1994

Interventions to reduce medicine prices

Impact of pricing regulations



Pharmaceutical Sector in 1994

Public Sector

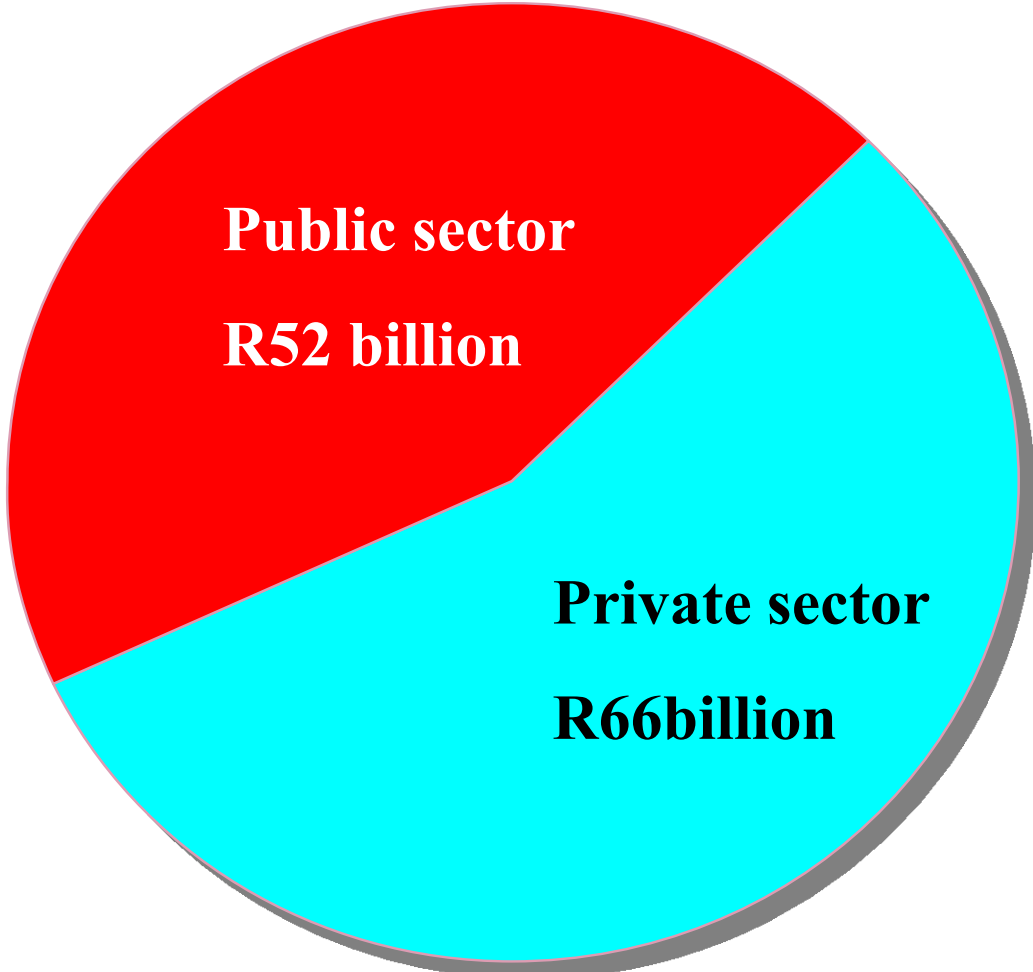
- Serves 38 million people
- Mainly essential drugs supplied
- 70% (volume) of medicine sales
- Medicine budget – R3billion
- Income based user fees – free to special groups
- < 50% of pharmacists work in the public sector serving 80% of population

Private Sector

- Essentially insured population – 7 million
- All registered drugs available
- 30% (volume) of medicine sales
- Medicine budget – R13billion
- High premiums – unaffordable
- Most pharmacists work in the private sector serving 20% of population

Context: Healthcare Financing, 2006

Serves 39
m
R1330pp



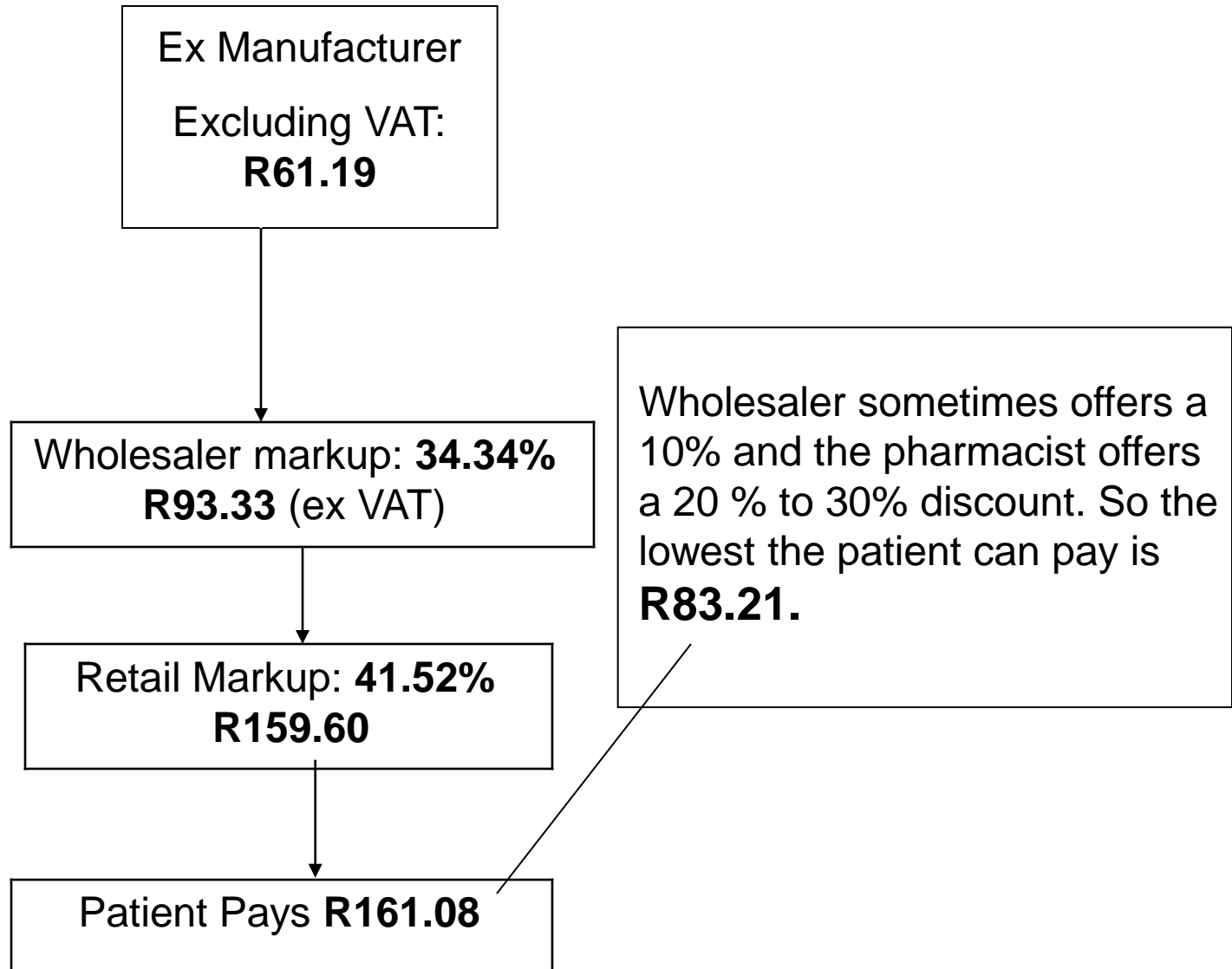
Serves 7 m
= R9428pp



Source: CMS and Treasury

Pricing Survey- (WHO/HAI)

Amoxicillin 250mg 500's



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Development of a National Drug Policy in 1996

- Generic substitution policy
- Establishment of pricing committee
- Single exit price for medicines
- Fixed fee for wholesalers
- Fixed fee for pharmacists
- Transparent pricing system
- No volume discounts, rebates or bonuses (18A)
- International benchmarking
- Reference pricing
- Pharmacoeconomics



Generic Substitution Policy

- Quality – assessed by medicine registration authority
- COMPETITIVE local manufacturing sector CRUCIAL
- Generic prices – 20-70% lower than patented drug price.
Fast Track registration for essential medicines.
- Generic substitution – “mechanism important”
 - SA, Canada – mandatory
 - Sweden, Germany – prescriber authorisation

Establishment of a Pricing Committee

- Minister appoints members
- Membership – DTI, Finance, Competition Commission, Pharmacists, Law, Consumer, Academics. No industry representation.
- Recommendations to Minister
- Secretariat - Pricing Unit in the Department of Health

Single exit price for medicines

- *Removal of rebates and discounts*
- Manufacturers sell at a single price irrespective of volumes
- No rebates, discounts or any other perversity
- Maximum price valid for a year
- Logistics fees must be transparent



Fee for Wholesalers

- Definition of logistics services
- Contracts between logistics providers and manufacturers
- Establishment of buying groups-CLAW BACK
- Differences between wholesalers and distributors



Fee for Pharmacists

- 26%/R26 – challenged by the retail pharmacy sector.
- Con. Court – review of the fee but upheld right to regulate.
- Request for information from retailers and other parties.
- Four tier fee structure
- Pharmacists have challenged the new fee
- Discussions with pharmacy groups resolve the matter.



Transparent Pricing System

- Printing of price on package
- Invoice to differentiate between SEP and price paid by patient
- Establishment of a website to access medicine prices
- Predictable price of a medicine throughout supply chain



International benchmarking (Originator)

- Basket of five countries
- Lowest price in the basket
- Average exchange rate in basket of countries
- Draft methodology published for comment.



Reference Pricing

Limits the price of an individual drug by comparison with the price of other drugs.

Basis for comparison:

- Same active ingredient
- Drugs in a pharmacological class
- Drugs with similar therapeutic effect

Most effective when there is a strong generics industry.

New drugs in the same pharmacological class/therapeutic class will be referenced using pharmacoeconomics.



Pharmacoeconomic Analyses

Pharmacoeconomics/ cost effectiveness analysis

Evidence based approach

Comparative effectiveness

Comparative safety

Direct and indirect costs

This method rewards true innovation – widely used in many countries.



Overview

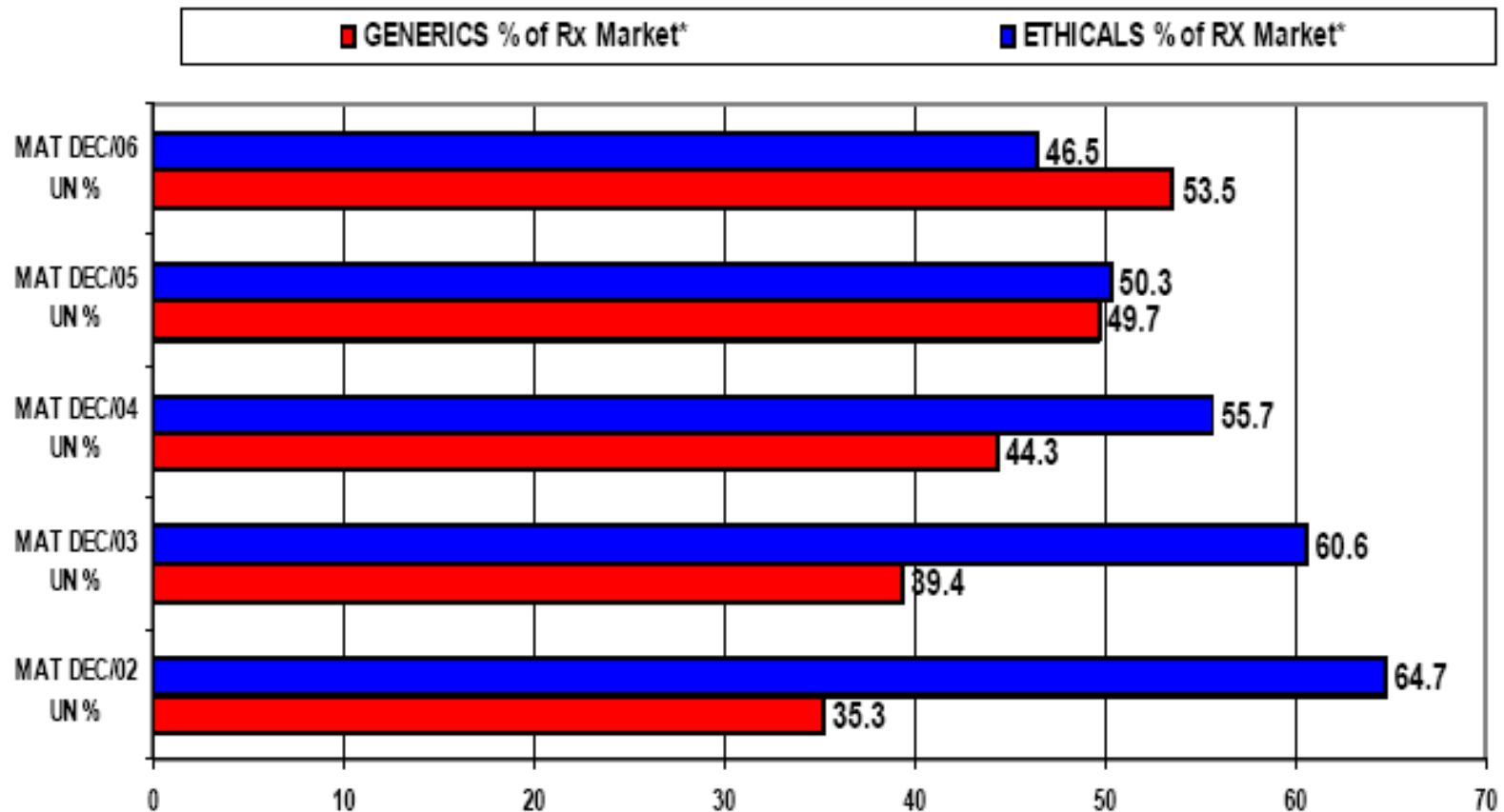
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Split between Generics vs Original medicines units – 5 Year trend



IMS SANDS TPM data as at Jan 2007 (SANDS: South African National Database)

Impact of pricing regulations

Generic substitution policy

- increased generic substitution – in excess of 30% utilisation
- greater incentive to introduce generics
- transfer of perversity from “Dr’s pen” to “pharmacist”

Pricing committee

- Attacks on the committee – media, lobbying etc
- Court challenges – technical and procedural
- appoint independent committee – technically competent
- no “stakeholder” representation
- technically competent secretariat
- Role of DTI, National Treasury



Impact of pricing regulations

Single exit price/ no rebates, discounts or bonuses

- No price discrimination between rural and urban
- Chain groups will not be able to access bulk discounts
- Reduction of medicine prices – average 19%
- Generics reduced by 25-30%
- Originators reduced by 12%
- Same unit price for different pack sizes – prevent risk transfer

Transparent pricing system

- Greater focus on price – more informed consumer – website, price on pack
- Price competition between manufacturers especially generics
- Pressure on supply chain margins – wholesaler/pharmacy



Impact of pricing regulations

Fixed fee for wholesalers

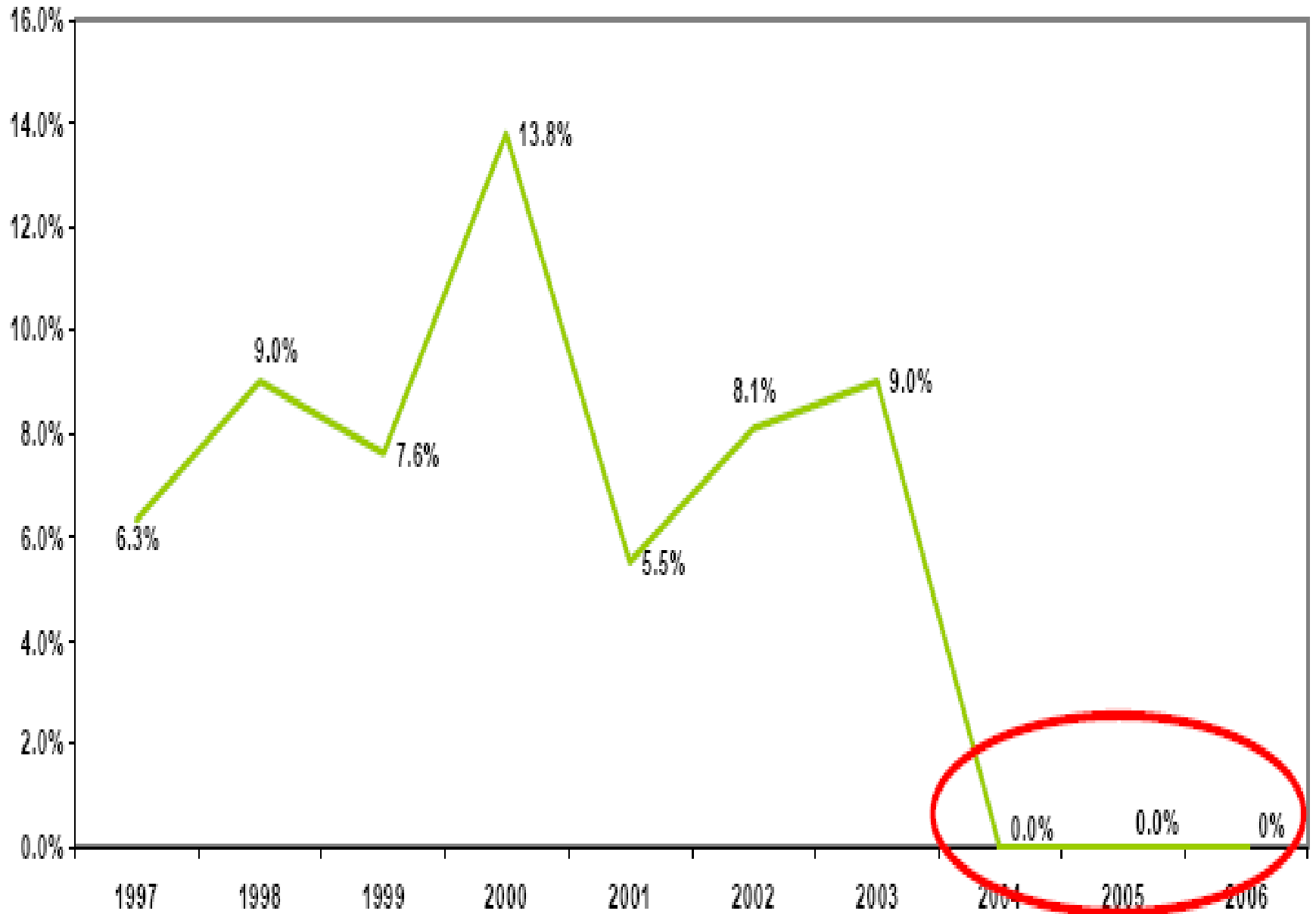
- Introduced logistics fee – “gaming” in absence of new fixed fee
- Wholesalers – buy drug and on sell – higher cost
- Distributors – no ownership – logistics services
- Wholesalers – generic distribution – efficiency??

Fixed fee for pharmacists

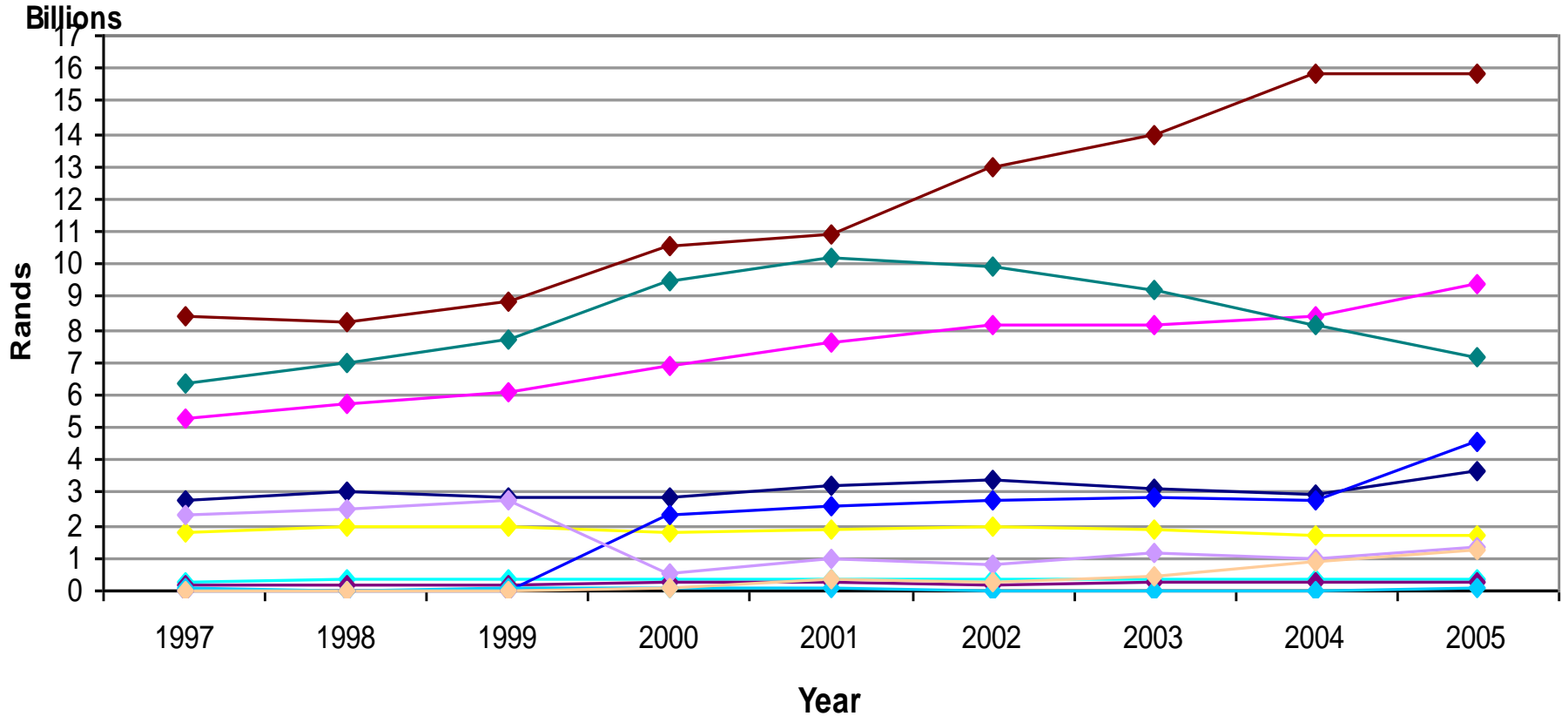
- Pharmacists do NOT supply cost data
- Challenge fee in court
- Markups of 35–40% requested
- 4 tier fee structure – higher % markup for generics



% Annual Average Price Increase



Trends in Total Benefits Paid, 1997 - 2005



- ◆ General Practitioners
- ◆ Dentists
- ◆ Provincial Hospitals
- ◆ Medicines
- ◆ Ex-Gratia Payments
- ◆ Capitulated Primary Care
- ◆ Medical Specialists
- ◆ Dental Specialists
- ◆ Private Hospitals
- ◆ Supplementary and Allied Health Professionals
- ◆ Other Benefits

Way Forward for IBSA Forum

- Sharing of drug price information between 3 countries
- Sharing sources of low cost drugs
- Sharing co effectiveness analysis of new drugs
- Sharing of training programmes that develop capacity in local production – linkages between universities in IBSA countries

Thank You



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