



Using regulation to strengthen drug access and quality A South African Perspective



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Balancing Treatment Access and Antibiotic
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South African Context

- Medicines Control Council – strong
 - Antibiotics dealt within this context – quality, safety and efficacy
- The Medicines and Related Substances Control Act 101 of 1965 (as amended)
 - Provision for registration and control of medicines
 - Licensing of professionals to dispense and manufacture them

Health Systems in SA

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



EDP

- The essential drugs concept, advocated by WHO through its Action Programme on Essential Drugs and PAHO, stresses availability, affordability, quality, and rational use of drugs. Five areas are central to reform strategy:
 - the roles of the public and private sectors,
 - drug financing alternatives,
 - pricing policies,
 - generics strategies, and
 - rational drug use.

Generic Substitution in South Africa

- Generic substitution (GS) became legal in 2003, and the Single Exit Price intervention was introduced in 2004
- Definition of GS
 - Substituting a generic drug for an identical brand-name drug that has lost its patent protection.
 - The dispensing of a chemically equivalent but less expensive drug in place of a brand-name product that has an expired patent.

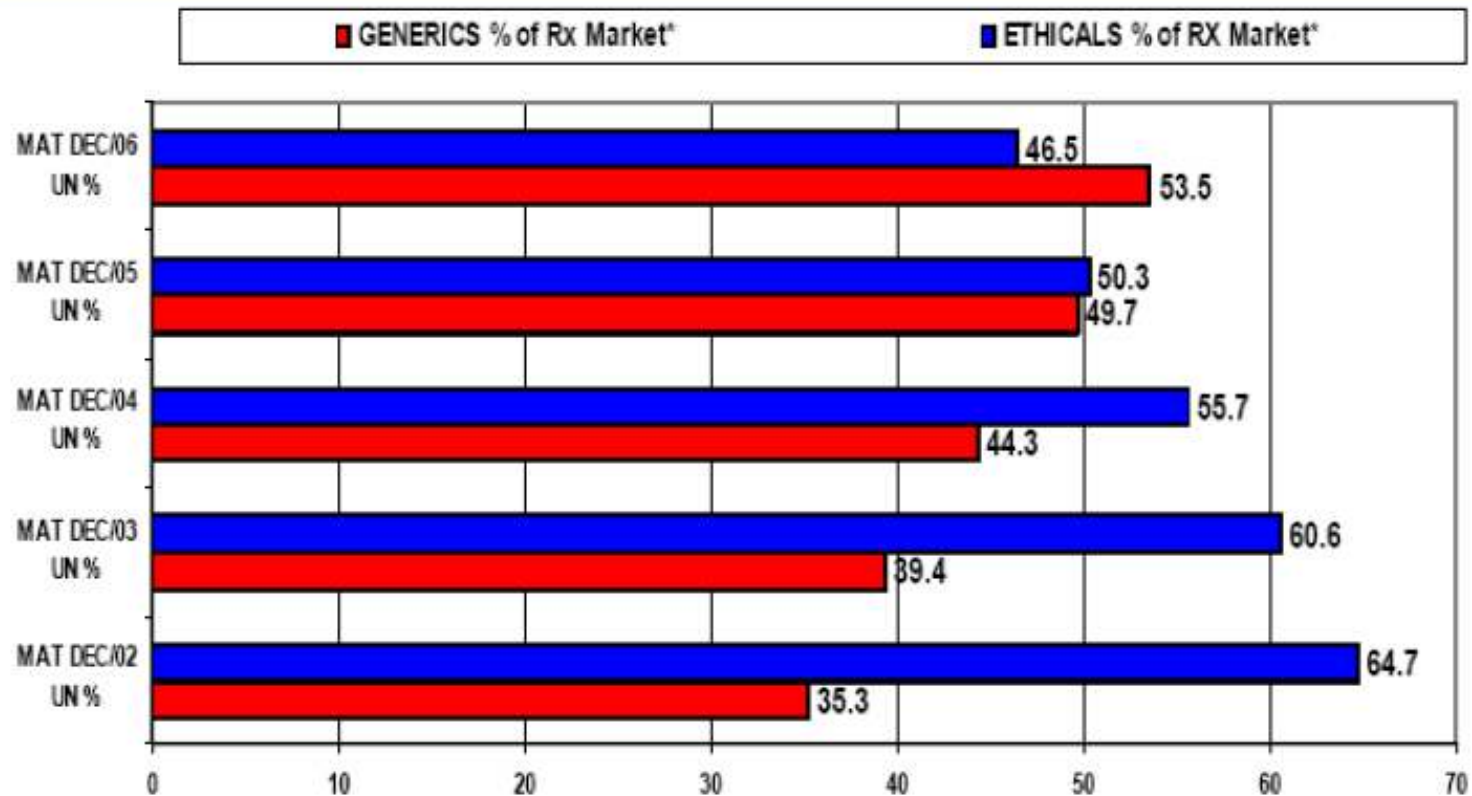


Generic Substitution

- 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

Impact

Split between Generics vs Original medicines units – 5 Year trend



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



GS (Cont)

- The Mediscor Medicines Review 2007 noted that “the use of generics is increasing steadily from 43% in 2005 to 46% in 2006 and to 47% in 2007”
- But what do the people think?
 - Aarti Patel, Robin Gauld, Pauline Norris and Thomas Rades. “This body does not want free medicines”: South African consumer perceptions of drug quality. *Health Policy and Planning* 2010;25:61–69



Consumer perception

- Irrespective of socio-economic status, respondents described medicine quality in terms of the **effect the medicine produced on felt symptoms**.
- Generic medicines, as well as medicines supplied **without charge** by the state, were **considered to be poor quality and treated with suspicion**.
- Respondents obtained medicines from three sources: **public sector hospitals and/or clinics, dispensing doctors and community pharmacies**.
- Generic substitution would be supported if the **doctor, rather than the pharmacist, recommended it**

Pricing Regulation in South Africa

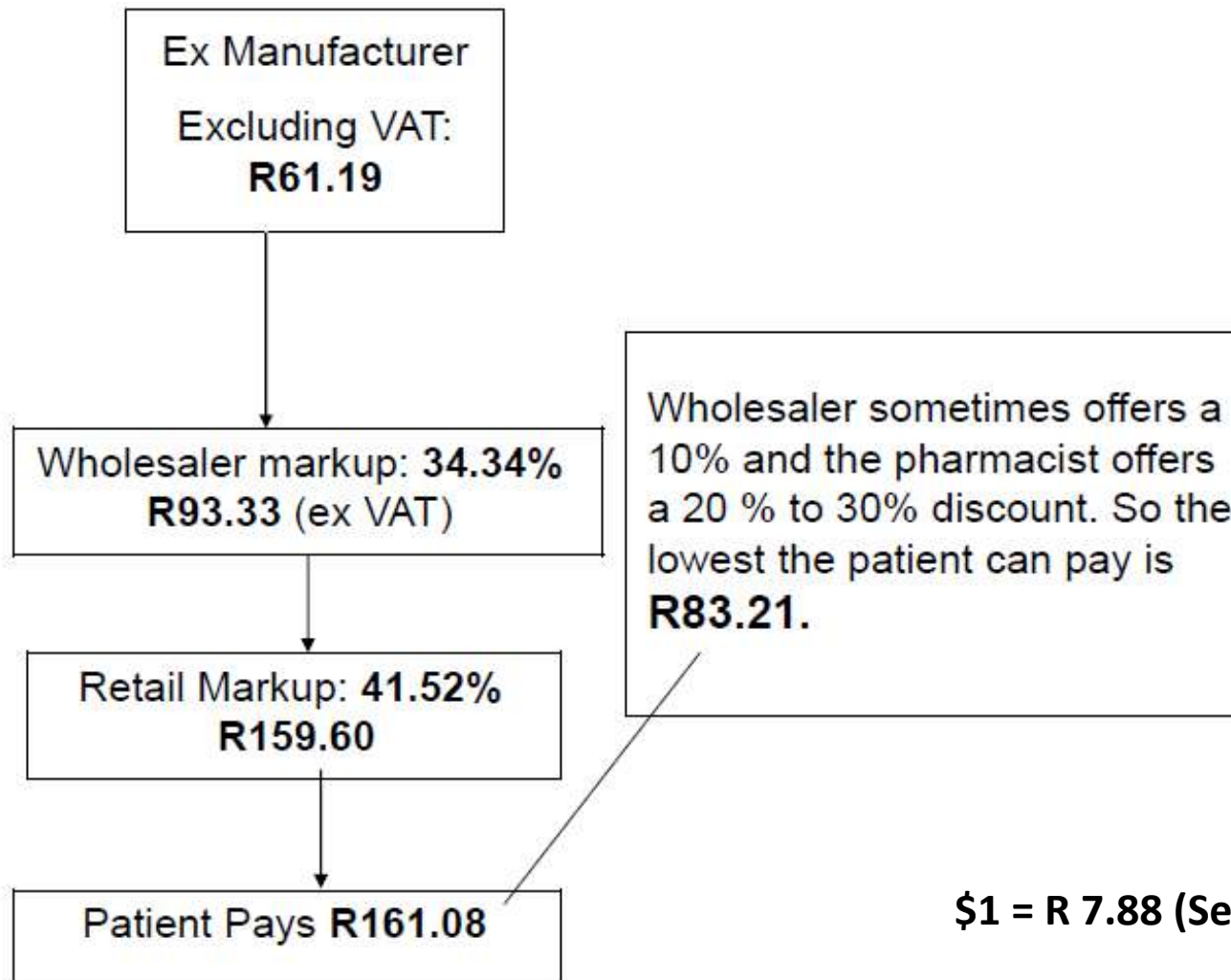
- South Africa's medicines law, the Medicines and Related Substances Act (Act 101 of 1965), was amended in 1997, with the introduction of two inter-related sections.
 - The first of these (section 18A) banned “bonusing” and the second (section 22G) created a “pricing Committee”.
 - It also provided for a “transparent pricing system”, which would include a “single exit price” (SEP).
- It stated that “such price shall be the only price at which manufacturers shall sell medicines ... to any person other than the State”, but that pharmacists and licensed dispensing practitioners (nurses and medical practitioners) would be allowed to charge a “dispensing fee”.

Impact of pricing regulations

- Single exit price/ no rebates, discounts or bonuses
- No price discrimination between rural and urban
- 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

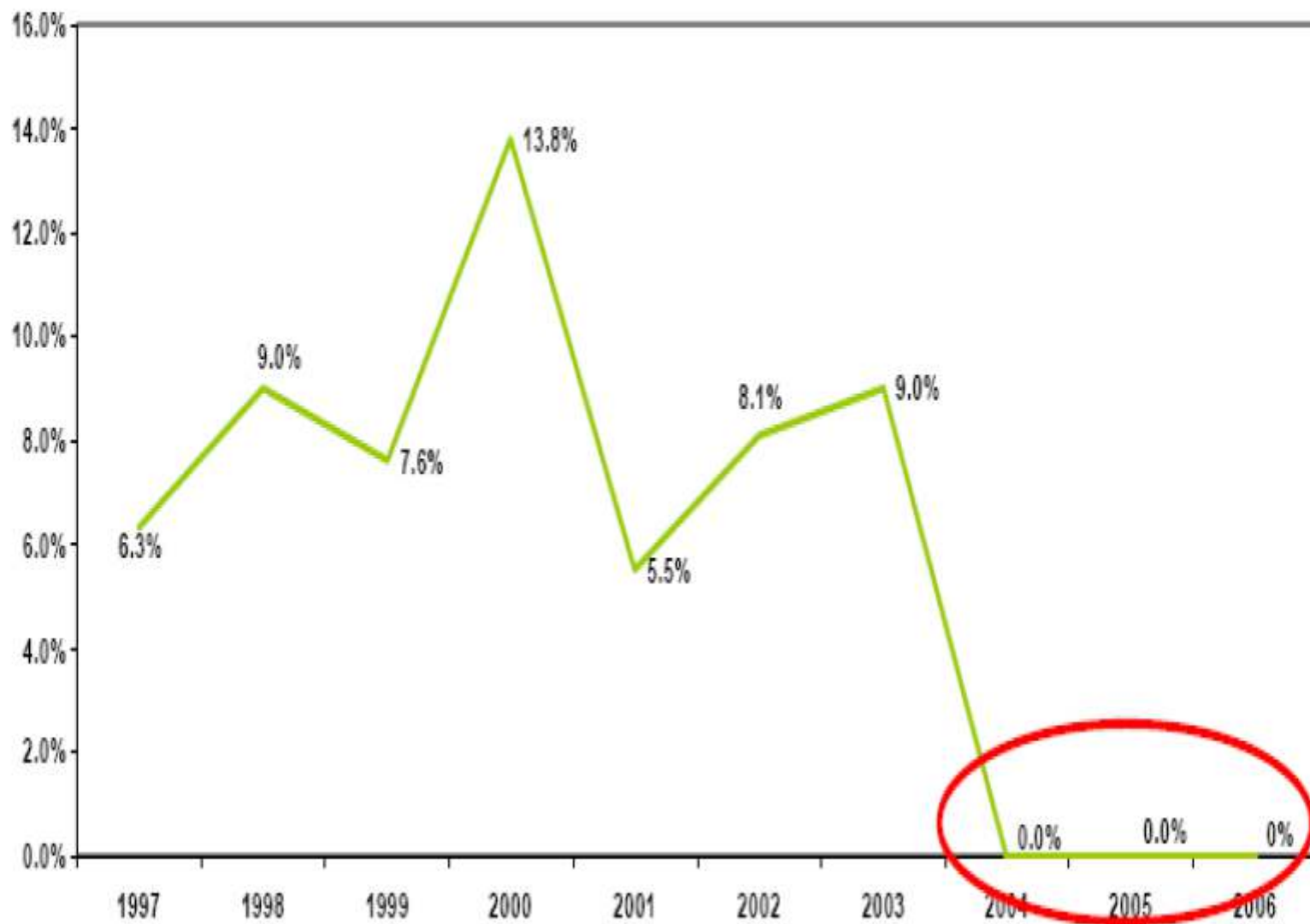
Pricing Survey-(WHO/HAI)

Amoxicillin 250mg 500's

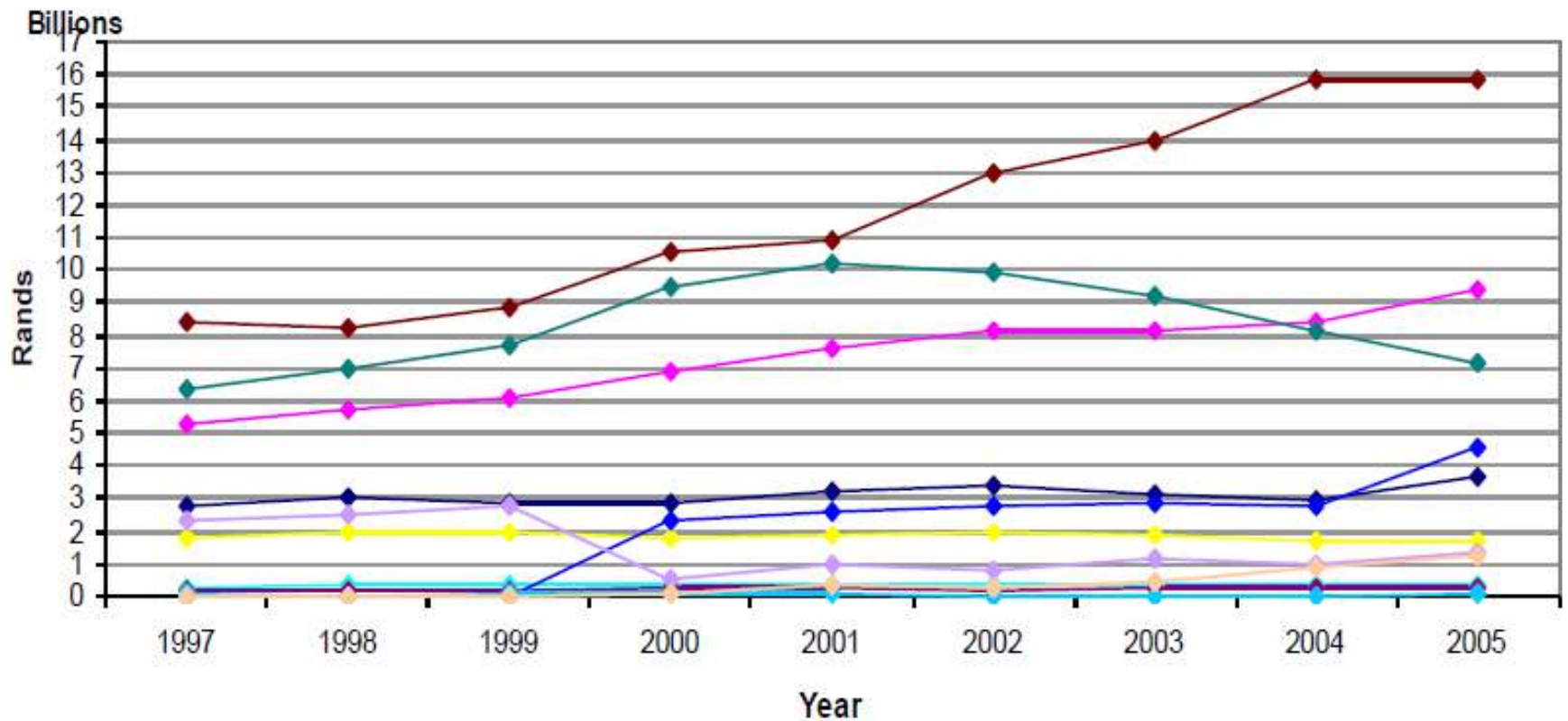


\$1 = R 7.88 (Sept. 2011)

% Annual Average Price Increase



Trends in Total Benefits Paid, 1997 - 2005



Source: Council for Medical Schemes



Future Trends

- South Africa has one of the highest rates of HIV and AIDS infections in the world, equivalent to just over 10% of the entire population.
 - As a result, the market for antiretroviral (ARV) drugs looks set to grow, particularly as the government looks at ways to increase the supply of these drugs via the public system.
- The government has also proposed a National Health Insurance (NHI) scheme, which aims to provide healthcare for all South Africans.
 - This is expected to become law in 2011, with the necessary institutional and organisational structures to start implementing the NHI being in place by March 2012.
 - The NHI will require compulsory contributions from all citizens, with the exception of the poor and unemployed



And Pharmaceutical Industry?

- Local manufacturers, notably Aspen Pharmacare and Adcock Ingram, almost exclusively produce generics.
 - Aspen completed the acquisition of the pharmaceutical division of an Australian company in January 2011.
- In September 2010, Ranbaxy opened a new manufacturing facility in Johannesburg.
 - The company aims to become a more significant provider to the state.



Thank You!