





SOUTH AFRICA

National Department of Health

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The pharmaceutical system in South Africa in the in- and out-patient private sector

Pricing policies for medicines

The National Drug Policy, Medicines and Related Substances Act, Pharmacy Act, Health Act, and Pricing Regulations contains regulatory measures which control the sale of medicines in South Africa.

Pharmacists and qualified dispensing practitioners like dispensing doctors can dispense any medicine that is sold in South Africa. Pharmacist's assistants, under the supervision of a pharmacist are allowed to dispense over the counter medicines. Nurses at clinics, usually in rural areas are allowed to dispense up to schedule 4, after getting permission from the South African Pharmacy Council and the Nursing Council.

The Single Exit Price (SEP) is the selling price for every medicine registered for sale in the private sector out patient. The SEP is the price that leaves the **manufacturer** site until it reaches the pharmacy or dispensing doctor facility. The only addition to the SEP is the dispensing fee which is included by the pharmacists or dispensing doctor at retail level at the point of dispensing

Previous SEP Adjustments

2004- 2007 → 5.21%

2008 → 6.5%



The dispensing fee is a maximum and can be discounted by the dispenser. The Single Exit price (SEP) however is not supposed to change at any stage throughout the supply chain other than where the manufacturer makes an application with the Department of Health to decrease their SEP either permanently or temporarily. The changed SEP should be available at the same price to all wholesalers. No rebates, discounts or incentive schemes are allowed in South Africa. SEP reviews are determined and announced by the Minister of Health annually.

Wholesale mark-ups/Logistics fees

Manufacturers and logistics service providers also referred to as wholesalers and distributors negotiate for the logistics fee. A contract should be in place for such agreements. A manufacturer may use as many logistics service providers as they wish which means different logistics service providers may be paid different fees by the same manufacture depending on the outcome of the negotiation and level of service. The logistics fee is expressed as a percentage of the ex manufacturer price.

Pharmacy mark-ups/Dispensing

The current Dispensing fee is arranged in a 4 tired structure. The dispensing fee paid by the consumer is dependent on the price of the medicine i.e. the SEP(See table below). The pharmacy mark up or dispensing fee is the only mark up to the price that leaves the manufacturer site, regardless of which wholesaler transported the medicine(s) to the pharmacy or any retailer.

Dispensing fee structure for South Africa: The exchange rate between the SA Rand and the US dollar is approximately 1\$ ~R7.5		
The SEP is the price of the medicine i.e. the Single Exit Price: In the SEP there is ex manufacturer price,logistics fee (distribution fee) and Vat.		
Dispensing Fee Tiers	SEP Range in rands	Dispensing Fee formula
Tier 1	R 0 -< R75.00	46% of SEP + R6.00
Tier 2	R75.00 - < R200.00	33%of SEP + R15.75
Tier 3	R200.00 -< R700.00	15%of SEP + R51.00
Tier 4	R700.00 -> R700.00	5% of SEP + R121.00

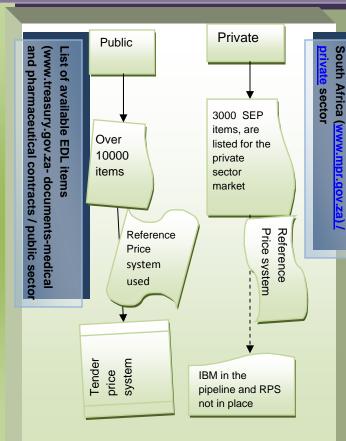
<u>VAT</u>

In South Africa, Vat is 14% for all commodities including medicines. Tax incentives given to the pharmaceutical industry are within the domain of the Department of Trade and Industry. These arrangements are not part of the Department of Health's mandate and therefore not covered in the Department of Health legislation. Department of Health policies are mainly supportive and protective of the consumer.

Reforms

Guidelines on Pharmacoeconomic Assessment of highly priced medicines especially new entities was published for comment in 2011. The Pharmaceoeconomic Guidelines are in the final stages of reassessment by the Department of Health, following comments from the pharmaceutical industry. South Africa has chosen Spain, New Zealand, Australia, South Africa and Canada as benchmark countries. Reimbursement in the South Africa private healthcare sector is performed by medical aid schemes in South Africa. Each medical aid scheme implements regarding the reimbursement policies

Database of Medicine Prices in



Co-payment

Copayments are charged to the patient that chooses a medicine that is priced higher than that which is on the PMB list of medicines for the medical scheme. The medical aid option to which the patient belongs also determines the extent of the copayment

Mechanisms for vulnerable groups

Children younger than 5 years, pregnant mothers, psychiatric patients and the elderly receive free care in public sector facilities in South Africa.

Pricing policies for medicines

Implementation of pricing policies at the in-patient sector is similar to that in the outpatient sector policies as described above, for the private sector. Affordability determines the amount paid by patients in the public sector. Some patient categories do not pay for health services in the public sector e.g. geriatrics, children under 5 and some psychiatric patients.

Wholesale mark-ups

In patient logistics fees or wholesale markups are determined similarly to the outpatient sector as described above.

Pharmacy mark-ups

In the private sector the system is the same for both inpatient and outpatient sectors as described above.

<u>VAT</u>

14% as described above