

# Operating in a Changing Environment

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South Africa

## Rationale for Legislation

- Health Sector Strategic Framework
  - Promote equity, accessibility, affordability and utilisation of health services
- National Drug Policy
  - Broaden access to safe and effective drugs at the lowest possible cost, in the public and private sector
  - Eliminate perverse incentives



# New Legislation

- Medicine and Related Substances Control Amendment Acts
  - Act 90 of 1997
  - Act 59 of 2002
  - Regulations

# Medicine Amendment Acts

## Generic Substitution: Section 22 F

Effective 2 May 2003

- Pharmacist must inform & dispense generic molecule, but not if:
    - physician writes “no substitution”
    - patient objects and is willing to pay the difference
    - if generic price is higher than branded product
    - product has been declared not substitutable
  - Definition of therapeutic equivalence strong
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- We support generic substitution with high quality generics after the patent on the original medicine expires
  - Competition among generics will generate savings

## Generic Substitution – What it is...

- A generic is a patent-expired medicine
  - Same active ingredient (i.e., enalapril)
  - Same strength
  - Same formulation
  - Same route of administration
  - Excipients may differ
  
- ONLY IF a generic is available, pharmacist must inform patient and dispense generic...
  - Patient may be asked to sign authorisation

### **EXCEPT IF...**

- The patient expressly forbids
- Doctor writes “no substitution”
- Price of generic is higher
- Product is declared not substitutable

## Generic Substitution – What it is not...

- There are no legal generics of patented medicines
- Patented medicines are not substitutable

FOR EXAMPLE...

- COZAAR cannot be substituted with a:
  - beta blocker
  - calcium channel blocker
  - ace inhibitor
  - or any other medicine in the same AIIA class



# Medicine Amendment Acts

## No bonusing, rebates or incentive schemes: Section 18A

### Delayed to 2 May 2004: Dependent on Pricing Committee

- No person shall supply a medicine according to a bonus, rebate or any other incentive scheme
  - Anticipated no volume discounts
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- We fully support these provisions intended to eliminate perverse incentives
  - Industry in confusion and increased perversity in 2003 due to delay

# Medicine Amendment Acts

## No sampling: Section 18B

**Effective 2 May 2003**

- No sampling is allowed
  - Exceptions for clinical trials, donations to State, tendering to the State and quality control, use at exhibitions as prescribed
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- Although sampling has been an important part of expanding access to medicines, this law seeks to prevent its abuse by banning it



# Medicine Amendment Acts

## Code of Practice for Marketing of Medicines: Section 18C

### Effective upon finalisation by Minister after public comment

- Part 1 - marketing of medicines to healthcare professionals
  - Discredit to & reduction in the Industry
  - Registration & prescribing requirements
  - Advertising, including internet
  - Information, claims, comparisons & disparaging references
  - Sponsorship (CME's)
  - Promotional material
  - Representative behavior
  - Gifts & inducements
  - Hospitality & Meetings
- Part 2 - marketing of medicines to the public
- Part 3 - marketing of complementary medicines (delayed)

# Medicine Amendment Acts

## Code of Practice for Marketing of Medicines: Section 18C

(continued)

- Enforcement through proposed Co-Regulation by Industry and Government
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- Fully supportive of new Code
  - Levels playing field
  - Extensive training required

# Medicine Amendment Acts

## Pricing Committee: Section 22 G

### **Delayed in practice: Operational when Minister appoints members**

- Committee will make recommendations on a transparent pricing system, including:
    - Single exit price (price review, excl. the state)
    - pharmacy dispensing fee
    - appropriate wholesaler/distributor fee
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- We fully support transparent prices and appropriate pharmacy/wholesaler/distribution fees to reduce excessive mark-ups
  - Linked with removal of perverse incentives (bonus & rebates)
  - Will level playing field

# Medicine Amendment Acts

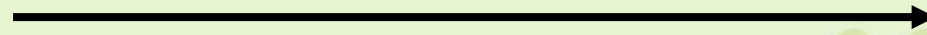
## Importation of Medicines: Section 15

**Effective 2 May 2003 yet guidelines to be finalised**

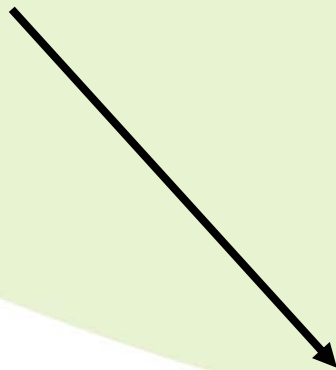
- Allows importation of patented medicine to South Africa if it can be located abroad at a lesser price
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- We support government's aims to promote access to affordable medicine, yet we are concerned that the safety of medicines imported under this law may be compromised if not carefully regulated and enforced

# Importation of Medicines

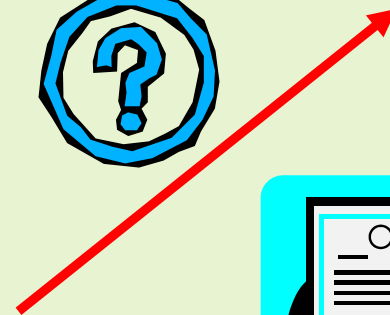
Europe



South Africa



Australia



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South Africa

# Medicine Amendment Acts

## Licencing of Dispensing Doctors: Section 22C

**Effective but delayed in practice until May 2004**

- Dispensing doctors required to have a dispensing license
- Beginning application process
- Supplementary Course accredited by SA Pharmacy Council after consultations



# Medicine Amendment Acts

## Various Regulatory Controls

- New scheduling (schedule 2 no longer advertised)
- Labelling, package inserts and patient information leaflet requirements to improve patient awareness and compliance with medicine
- Expedited registration process for essential medicines
- Further clarification will come from the MCC

## Consequences of Failure to Change

- Public outrage
- Review of legislation and over-regulation
- Loss of reputation for individual and company
- Legal investigation
- Undermining of investor confidence
- Disruption of business

