



making health law work for you

Dynamic legislative developments

The Constitutional Context

- Rule of law (*it is not about who, it is about what the law says*)
- If interpreted by Courts, that IS the law
- Section 27 – right of access to healthcare
- Section 7 – the state must fulfil these rights
- Section 8 – binds all organs of state

Other relevant laws

- **Consumer Protection Act:**
 - Co liable for harm caused – unclear /incomplete instructions (e.g. side-effect not included on PI) & lack of warnings
- **Hazardous Substances Act:**
 - Now included in definition of a medical device, BUT Haz Subst Act NOT amended and still duty of DG and NDoH
- **National Regulator for Compulsory Specifications**
- **Foodstuffs, Cosmetics & Disinfectants Act**
 - A disinfectant of a device included in definition of a device in Act 14 of 2015



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Act 14 of 2015 (Bill 6D of 2014)

NOTE:

Section numbering used as it would be in Act 101 of 1965 after being amended by Act 72 of 2008 and Act 14 of 2015

Exception transitional provision in Act 14 of 2015 (i.e. s26 of Act 14 of 2015)

Four pieces of amendments

- Medicines Amendment Act 72 of 2008
 - Published and signed, but not yet proclaimed
- Medicines Amendment Act 14 of 2015
 - Published, signed, not proclaimed
- Draft Device Regulations, July 2015
- Draft Device Guidelines, Aug 2015, deadline for comment 30 November 2015

What we still need

- Device Regulations as final
- General Meds Regs amended (*it still contains references to devices and Pricing Committee – which would need to expand to include devices*)
- General Regs (*on appeals, Pricing Committee, etc.*) on general matters for medicines and medical devices
- Regs on s18A (bonus, rebate, incentive scheme), 18B (sampling for appraisal purposes)

2. Establishment of South African Health Products Regulatory Authority

(1) The South African Health Products Regulatory Authority is hereby established as an organ of state within the public administration but outside the public service

...

(5) The Authority acts through its Board.

Committees

- SAHPRA Board may appoint Committees (s2H) – functions (s2B):
 - Evaluation or assessment – quality, safety, efficacy and performance
 - Registering **timeously**
 - Re-evaluate or re-assess
 - Ensure vigilance
 - Ensure trials – assessed
 - **Liaise & exchange info; enter into agreements – other authorities**
- But CEO shall, in consultation with Board also appoint Committees (s3(9))

+ **S35(1)(xlili)**: regs “relating to **time frames** for the consideration of applications by the Authority”

Registration process (s14 and s15) & transition (s26 of Act 14 of 2015)

- Based on call-ups (as in past)
 - Scheduled substances? (s22A & next slide)
- No more fast-track
- Registration pending at time of – effect, dealt with as if amendments not in place
- Registration done under unamended Act – stays as was done

In Parliament last year

(extract: PMG minutes)

*Dr Gouws said that when one looked at the regulation on scheduled substances, it talked about fees which were paid to the Authority for the registration of medical devices and IVDs, and this also included the registration of scheduled substances. **The Authority was not intent on registering a scheduled substance**, since it was an active ingredient -- they could not register a substance that was used to make medicine. **The Bill would be registering only medicines, and not substances ...***

Licensing – s22C and 22H

- Manufacturer, wholesaler, distributor – licence
- Wholesalers may only purchase from “original manufacturer or from the primary importer”
- Longer & different supply chain in devices (*distributor is not a logistics provider (only)*)

Pricing

- s18A: regs “in consultation with Pricing Committee” on bonus, rebates and incentive schemes – medicines, devices & IVDs
- S36: exemption from 18A (*all products*) and 22G (*only meds*) by Minister “on recommendation of Pricing Committee”
- s18B: sampling only for appraisal purposes, as per regulations (*by MoH & SAHPRA – s35, not Pricing Committee / MoH*)
- Appeals: no provision to appeal against Pricing Comm or MoH (s24 and 24A)

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