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# The amended Medicines Act and its challenges …

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   - Clinical trials of devices
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# When do laws come into effect?

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# MEDICINES AND RELATED SUBSTANCES AMENDMENT ACT NO. 14 OF 2015

[ASSENTED TO: 24 DECEMBER, 2015]
[DATE OF COMMENCEMENT: 1 JUNE, 2017]

(Unless otherwise indicated)

*(The English text signed by the President)*

Confusion: “commencement date”, versus Council continuing with functions until Board is there…

# MEDICINES AND RELATED SUBSTANCES AMENDMENT ACT NO. 72 OF 2008

[ASSENTED TO 19 APRIL, 2009]
[DATE OF COMMENCEMENT: 1 JUNE, 2017]

*(English text signed by the President)*

This Act was published in *Government Gazette* 40869 dated 26 May, 2017.

**as amended by**

Medicines and Related Substances Amendment Act, No. 14 of 2015

# The Interpretation Act

**13. Commencement of laws.**-(1) The expression "commencement" when used in any law and with reference thereto, means the day on which that law comes or came into operation, and that day shall, subject to the provisions of subsection (2) and unless some other day is fixed by or under the law for the coming into operation thereof, be the day when the law was first published in the *Gazette* as a law.

(2) Where any law, or any order, warrant, scheme, letters patent, rules, regulations or by-laws made, granted or issued under the authority of a law, is expressed to come into operation on a particular day, it shall be construed as coming into operation immediately on the expiration of the previous day.

(3) If any Act provides that that Act shall come into operation on a date fixed by the President or the Premier of a province by proclamation in the *Gazette*, it shall be deemed that different dates may be so fixed in respect of different provisions of that Act.

[Sub-s. (3) added by s. 10 of Act No. 129 of 1993 and amended by s. 7 of Act No. 201 of 1993.]

**INTERPRETATION ACT**
**NO. 33 OF 1957**

[View Regulation]

[ASSENTED TO 16 MAY, 1957]
[DATE OF COMMENCEMENT: 24 MAY, 1957]

*(English text signed by the Governor-General)*

This Act has been updated to *Government Gazette* 15467 dated 28 January, 1994.

From the commencement date we apply THE AMENDED Medicines Act

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# Should we, or shouldn't we, bring it into effect?

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# Health Department on its Annual Performance Plan

Health

04 May 2017

Chairperson: Ms M Dunjwa (ANC)

Dr P Maesela (ANC) noted that with grants given to the provinces by the National Department, the Committee had been suggesting the funds could be used for infrastructure revitalisation - this would help a lot. In th two to three years all tertiary institutions could be revitalised and there would be progress. How much infrastructure had been revitalised thus far. He requested the Committee be updated as to why there were probl with SAHPRA (South African Product Regulatory Authority), and when will the CEO get appointed.

With regards to SACRA, this was a sequencing issue. There was a hanging legal issue where one stakeholder group said regulations could not be published without proclamation of the Act while other stakeholders we saying the opposite. The Minister must make regulations in consultation with the board but the board was not yet established so there were two contrary opinions. The Department, however, decided to go ahead wit publishing of the regulations while the Act would be proclaimed at a later stage. The advert for the board would soon be out. Proclamation would be awaited as the regulations were ready. Appointment of the CEO co then begin.

# How laws look if we only bring parts into effect, to:

… create structures and to do regulations BEFORE rest is brought into effect

**PROTECTION OF PERSONAL INFORMATION ACT**
**NO. 4 OF 2013**

[ASSENTED TO 19 NOVEMBER, 2013]
[DATE OF COMMENCEMENT TO BE PROCLAIMED]

(Unless otherwise indicated)

*(The English text signed by the President)*

This Act has been updated to *Government Gazette* 37544 dated 11 April, 2014.

**39. Establishment of Information Regulator.**—There is hereby established a juristic person to be known as the Information Regulator, which—

(*a*) has jurisdiction throughout the Republic;

(*b*) is independent and is subject only to the Constitution and to the law and must be impartial and perform its functions and exercise its powers without fear, favour or prejudice;

(*c*) must exercise its powers and perform its functions in accordance with this Act and the Promotion of Access to Information Act; and

(*d*) is accountable to the National Assembly.

(Date of commencement of s. 39: 11 April, 2014.)

**ublic and private bodies; to**
**r the processing of personal**

To do this:

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(2) After complying with subsection (1) and after consultation with the Regulator in respect of the draft regulations referred to in section 112, the Minister may—

# Does the absence of regulations automatically make the sections of the Act to be not in effect

Two Constitutional Court cases on this:

- SAMDDRA Act (2000)
- National Health Act's Certificate of Need (2015)

- If sections are brought into effect without proper regulations, etc. – approach Constitutional Court to invalidate Presidential Proclamation

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# How do we interpret (i.e. read and understand) laws?

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# The Rule of Law (RoL)

- Is a fundamental tenet in our constitutional democracy
- It is not about anyone giving anyone permission to do anything, it is whether the law allows for (a) such permission and (b) such an interpretation

- RoL, also is:
  - Legal certainty
  - Consistency
  - Equal application of the law (level playing field)

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# Statutory interpretation rules = law!

- Use the words, in context
  - The law means what is says, e.g. if it says “registered medicines”, it means registered; if it just says “medicines” it means “medicines”
  - You CANNOT read words into legislation (only done by CC to give effect to constitutional rights)
- Cannot interpret one section so that it nullifies another section, make that section superfluous or unnecessary
  - e.g. s21 cannot be read so as to obviate compliance with s18A and B, for example

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# On Acts and regulations

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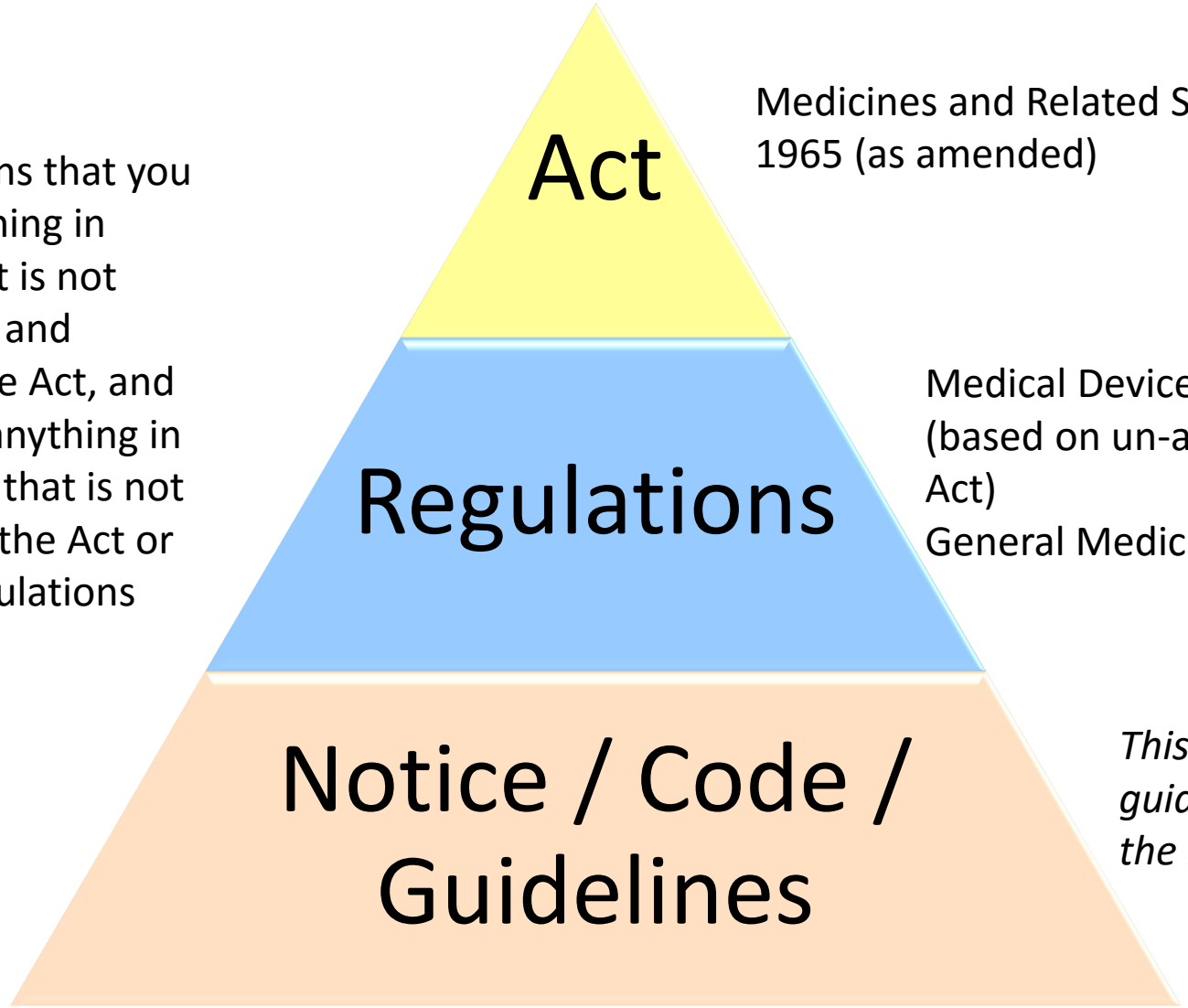
# Hierarchy of laws pertaining to health products

**Ultra vires** means that you cannot do anything in Regulations that is not empowered by, and aligned with, the Act, and you cannot do anything in Guidelines, etc. that is not empowered by the Act or the aligned Regulations




Medicines and Related Substances Act, 1965 (as amended)

Medical Device Regulations, 2016 (based on un-amended Medicines Act)
General Medicines Regulations, 2017

*This is NOT law, should guide implementation of the law*

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CONSTITUTIONAL COURT OF SOUTH AFRICA

Case CCT 201/14

# CC to the rescue…. (CON, 2015)

[1] This is an application for direct access in terms of section 167(6)(a) of the Constitution.[1] The matter concerns the premature promulgation of a proclamation bringing certain sections of the National Health Act[2] into operation.

[2] The President, the Minister in the Presidency, the Director-General in the Presidency, the Minister of Health and the Director-General of the Department of Health (the applicants) maintain that the President's decision to bring the provisions into operation was made in error and was therefore irrational in law. They seek an order declaring the Proclamation[3] invalid and setting it aside. The South African Dental Association (SADA) and the Hospital Association of South Africa (HASA) are cited as respondents in this matter. They support the relief sought by the President. Indeed, it was SADA who brought the alarming situation that necessitates this application to the attention of the Presidency.

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holding a certificate of need. The National Health Act authorises the Minister of Health (the Minister) to prescribe regulations regarding applications for, and the granting of, certificates of need.[5] These regulations are not yet in place.

[4] The consequence is that health service providers in South Africa are currently engaging in criminal conduct, as no individual or entity that provides health services is in a position to obtain the required certificate of need as long as the regulations have not taken effect.

[5] The President approached this Court directly to rectify this.[6] He submits that the regulations, which do not yet exist, form an essential part of the legislative scheme.

# The SAMMDRA Act being brought into effect in error: CC ruling

1999[1] and Government Notice R567 of 1999.[2] Proclamation R49 was issued by the President and purported to bring into operation the South African Medicines and Medical Devices Regulatory Authority Act, 132 of 1998 (the Act).[3] Government Notice R567 was issued by the Minister of Health and purported to provide schedules to the Act in terms of section 31 read with section 54 of the Act.

the 1965 Act are specifically repealed.[6] The Act makes provision for the determining of new schedules and the making of regulations by the Minister.[7] It establishes the South African Medicines and Medical Devices Regulatory Authority (the Authority)[8] which is to be governed by a board appointed by the Minister in accordance with the provisions of the

According to the affidavit, the regulatory base necessary for the operation of the Act was not in place when Proclamation R49 was published because schedules had not been made to replace the repealed schedules of the 1965 Act, and other essential regulations contemplated by the Act had not been made.

[8] Concerned to avoid the consequences of bringing the Act into force prematurely, the applicants applied to the High Court as a matter of urgency for an order declaring that the Proclamation and the Government Notice were invalid.

- **Long and short of it:** we must follow the law. The law (on bringing things into effect when we are not ready), as interpreted by the CC, says we must go to court, not IGNORE, or act on official's recommendations, to ignore the law for now!

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# So, lets look at a few sections and regulations in the “new" Medicines legislation

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# Example 1: s18A and 18B

| Section | Affects | What is prohibited / permitted | Regs envisaged? | Entities involved |
|---|---|---|---|---|
| 18A(1) | Meds, device, IVD | No Bonus, rebate, incentive scheme | No | DoH to enforce (s29 – criminal offence to violate) |
| 18A(2) | Meds, device, IVD | Acceptable and unacceptable | Yes | MoH in consultation with PC |
| s18B | Meds, device, IVD | No sampling, i.e. no free supply whatsoever # | **No** | DoH to enforce (s29 – criminal offence to violate) |
| s18B | Meds, device, IVD | Can supply to "appraise" | Yes | MoH in consultation with SAHPRA |

| Exemptions (industry or product or group) | From what? | Who grants it? |
|---|---|---|
| 36(1) | Any section in the Act, can set conditions | MoH in GG on recommendation of SAHPRA |
| 36(2) | Section 18A or 22G… but only for meds & scheduled substances (*drafting mistake?)* | MoH in GG on recommendation of PC |

PC = Pricing Committee

#In past s18B said *"does not include the free supply of medicines for the purposes of clinical trials, donations of medicines to the State, tendering to the State and quality control by inspectors"*. So yes, free supply to state was always excluded from prohibition in the past, but not anymore… (*was it a drafting mistake?)*

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# Exemptions (s36): as only option?

**36. Exclusion of any medicine, Scheduled substance, medical device or IVD from operation of Act.**—(1) The Minister may, on the recommendation of the Authority, by notice in the *Gazette* exclude, subject to such conditions as he or she may determine, any medicine, Schedule substance, medical device or IVD **from the operation of any or all of the provisions of this Act**, and may in like manner amend or withdraw any such notice.

(2) Notwithstanding subsection (1), the exclusion of any **medicine or Scheduled** substance from the operation of **sections 18A and 22G** shall be effected by the Minister on the recommendation of the Pricing Committee.

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# If s18A and 18B only apply to “registered” medicines:

- Old Medicines = can bonus, can sample, etc.
- Unregistered medicines = can bonus, rebate and incentive scheme, sample
- Unregistered medicines = no need to push for registration, as unregistered can be commercialised (as long as we don’t market)
- If registered, you can never give trial medicines for free, and can never provide the diagnostics and devices for free even when used with an unregistered medicine
- Donations: Yes, if unregistered; No if registered
- For medical devices & IVDs: what do we do once they are registered?

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# Interpretational tapdances …

- Create a system that does not make sense
- Provide short-term relief (e.g. on “if you use a device to administer a medicine, you can go ahead as the device is (for now) unregistered):
  - What are we going to do once the devices ARE registered?
  - Is I fair that those then who are registered first, are commercially disadvantaged first?
- Does not solve the issues of clinical trials, donations and state tenders, nor provision for QA purposes

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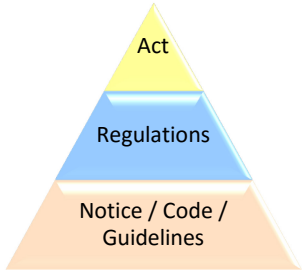
# Example 2: s22H and reg 25 (Genl Regs, 2017)




- **Reg 25. ”Exemption in terms of section 22H.**—(1) A wholesaler desiring to buy medicines from another wholesaler shall apply to the Director-General for an exemption referred to in section 22H (3) of the Act.”

- What does section 36 of the Act say? Who grants exemptions…

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# Example 3: Section 14(3) v Reg 28 (Med Dev)

- **28. Transitional arrangements regarding unregistered medical devices and IVDs.**—(1) An unregistered medical device or IVD sold in the Republic at the time of the commencement of these Regulations is, subject to regulation 8, considered to be sold legally until such time as the call-up notice period referred to in sub-regulation (2),for the medical device or IVD, has expired.

*vs*

- **14 (3)** In the case of a medicines, medical device or IVD which was available for sale in the Republic immediately prior to the date of publication in the *Gazette* of the declaration by virtue of which it is subject to registration in terms of this Act, the provisions of subsection (1) shall come into operation

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# Example 4: Clinical trials of devices

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**INTERPRETATION ACT**
**NO. 33 OF 1957**

[View Regulation]

[ASSENTED TO 16 MAY, 1957]
[DATE OF COMMENCEMENT: 24 MAY, 1957]

*(English text signed by the Governor-General)*

This Act has been updated to *Government Gazette* 15467 dated 28 January, 1994.

- Reg 16 (Med Dev) came into effect 9 Dec 2016 … or not?
- However, stakeholders informed that only trials from 1 June 2017 should be registered
- Are we saying the device regs are ultra vires and had / have no proper empowering framework? Section 35 in old Act not enough? If we say that, ALL applications of 24/8/2016 are invalid….

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# Pricing Regulations: some questions

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# Examples of issues

1. “You are out of time with your SEP increase application and must now do a reg 9”

2. “You are the RP and you are responsible for pricing of medicines”

3. “Your price is too high, we are not approving it”

# 1. Regulation 8(3):

(3) Subject to the provisions of reg 8 (1) *(i.e. the quantum)*, … may no more than once a quarter increase the single exit price … within a year provided that —

(i) such increase does not exceed the single exit price of the medicine or scheduled substance as first published in respect of that year;

(ii) the increase in the single exit price is applied to all sales of the medicine or Scheduled substance and not to selected categories of purchasers;

(iii) the manufacturer or importer **notifies the Director-General of the increase in the single exit price at least 48 hours prior to the implementation of such increase**;

(iv) … not be increased within … six months commencement of these regulations.

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# 1. Regulation 9

**9.** (1) The Minister may, in exceptional circumstances, authorise …, on written application … increase the price … by a specified amount greater than that permitted in terms of regulation 8.

(2) In considering an application … the Minister must take into account—

(*a*) the nature and extent of any adverse financial, operational and other circumstances …;

(*b*) the effect, if any, on the availability of the medicine …;

(*c*) the nature of the health condition for which the medicine … is a registered … public health would be adversely affected;

(d) the extent … section 27 (1 ) (*a*) and 27 (3) of the Constitution may be adversely affected or limited …

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# 2. RP’s duties….

# 3. So if there are no price approval processes, how are prices “controlled”?

- Through transparency, but also:

- Reg 14, 15, 22 and 23 – unreasonable price process:
  - Info to be requested by the DG
  - Provided to DG in 30 days, unless not in co’s possession
  - DG process of declaring a price, with prescribed conditions to be considered and only then declared unreasonable in GG

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# THANK YOU!

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