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Challenges and opportunities for pharmacy

Outline:

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1. What is technology? Legal definitions
2. Who pays, and what for technology? The race between law, technology and funding
   - CMS Annual Report
   - Health Market Inquiry (HMI)
3. Amendment Acts 72/2008 and 14/15
   - Licensing
   - Registration
   - Commercial matters

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What is “technology”?

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- **National Health Act, 2003:**
  - **“health technology”** means machinery or equipment that is used in the provision of health services, but does not include medicine as defined in section 1 of the Medicines and Related Substances ~~Control~~ Act, 1965 (Act No. 101 of 1965)
  - S90(1) (1) The Minister, after consultation with the National Health Council or the Office, as the case may be, may make regulations regarding — (*r*) health technology

What is “technology”?

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- Medicines Act, 1965:
  - Amended by Acts 72 of 2008 and 14 of 2015

Current definition:

- “**medical device**” means any instrument, appliance, material, machine, apparatus, implant or diagnostic reagent—

  (*a*) used or purporting to be suitable for use or manufactured or sold for use in—

  (i) the diagnosis, treatment, mitigation, modification, monitoring or prevention of disease, abnormal physical or mental states or the symptoms thereof; or

  (ii) restoring, correcting or modifying any somatic or psychic or organic function; or

  (iii) the diagnosis or prevention of pregnancy,

- Current definition (continued):

  and which *does not achieve its purpose* through chemical, pharmacological, immunological or metabolic means in or on the human body but which may be assisted in its function by such means; or

  (*b*) declared by the Minister by notice in the *Gazette* to be a medical device,

  and includes any part or an accessory of a medical device

  – New definition (Acts 72 and 14): similar (align IMDRF), and adds:

    (iv) supporting or sustaining life

    (vi) disinfection of medical devices; or

    (vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body

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The race between law, technology … AND FUNDING

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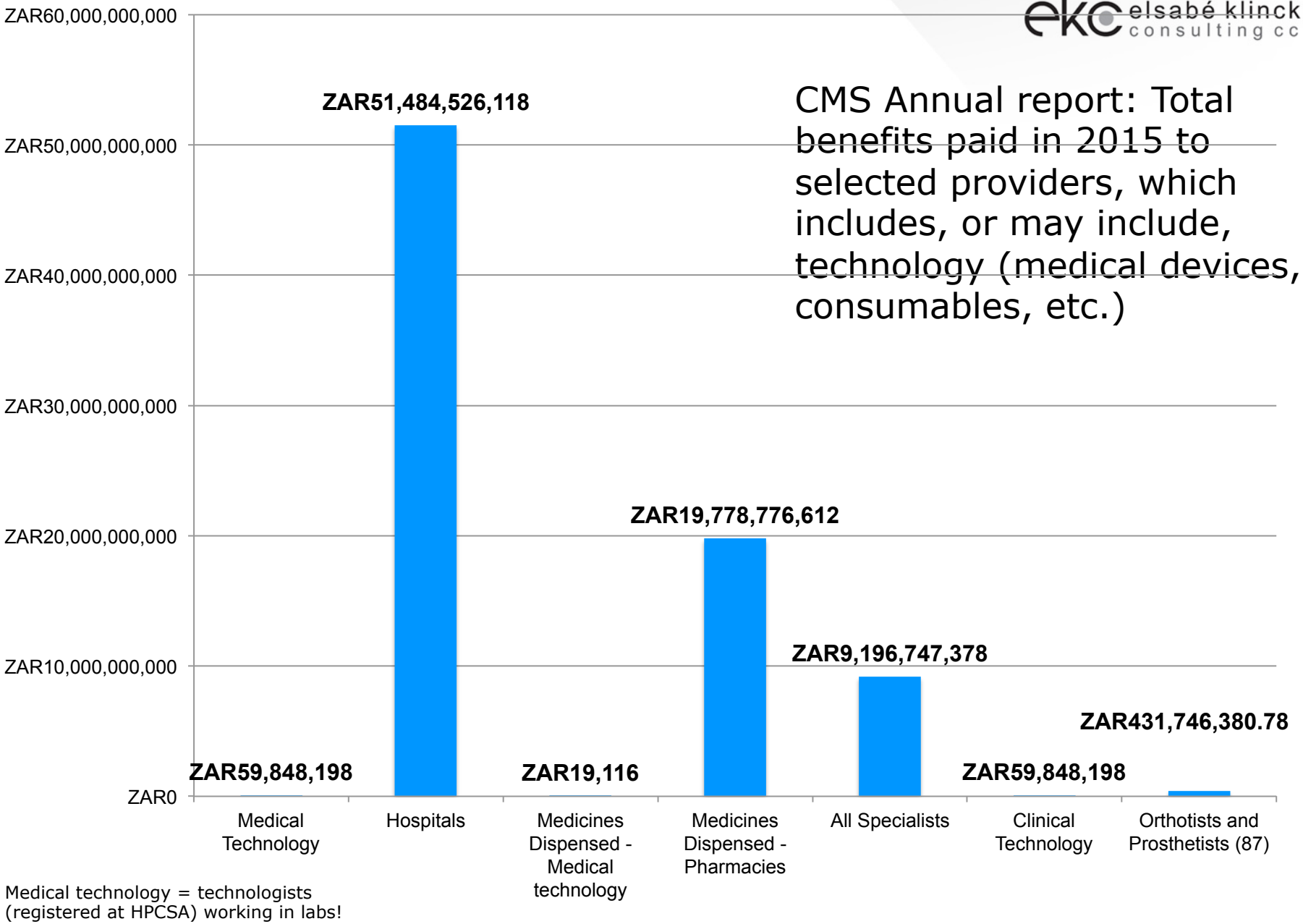
CMS Annual Reports

Role of technology in medical schemes environment

- Not always separately recorded, and can be included in:
  - Professional fees and/or ward fees
  - Professional equipment / technology use fees
  - Professional “hire-fee” fees
  - Global fees
  - Part of business expenses (similar to a printer, computer and software)
- But what we DO know (“kind-of…”):



CMS Annual report: Total benefits paid in 2015 to selected providers, which includes, or may include, technology (medical devices, consumables, etc.)

Medical technology = technologists (registered at HPCSA) working in labs!

Last breakdown of hospitals (2013)

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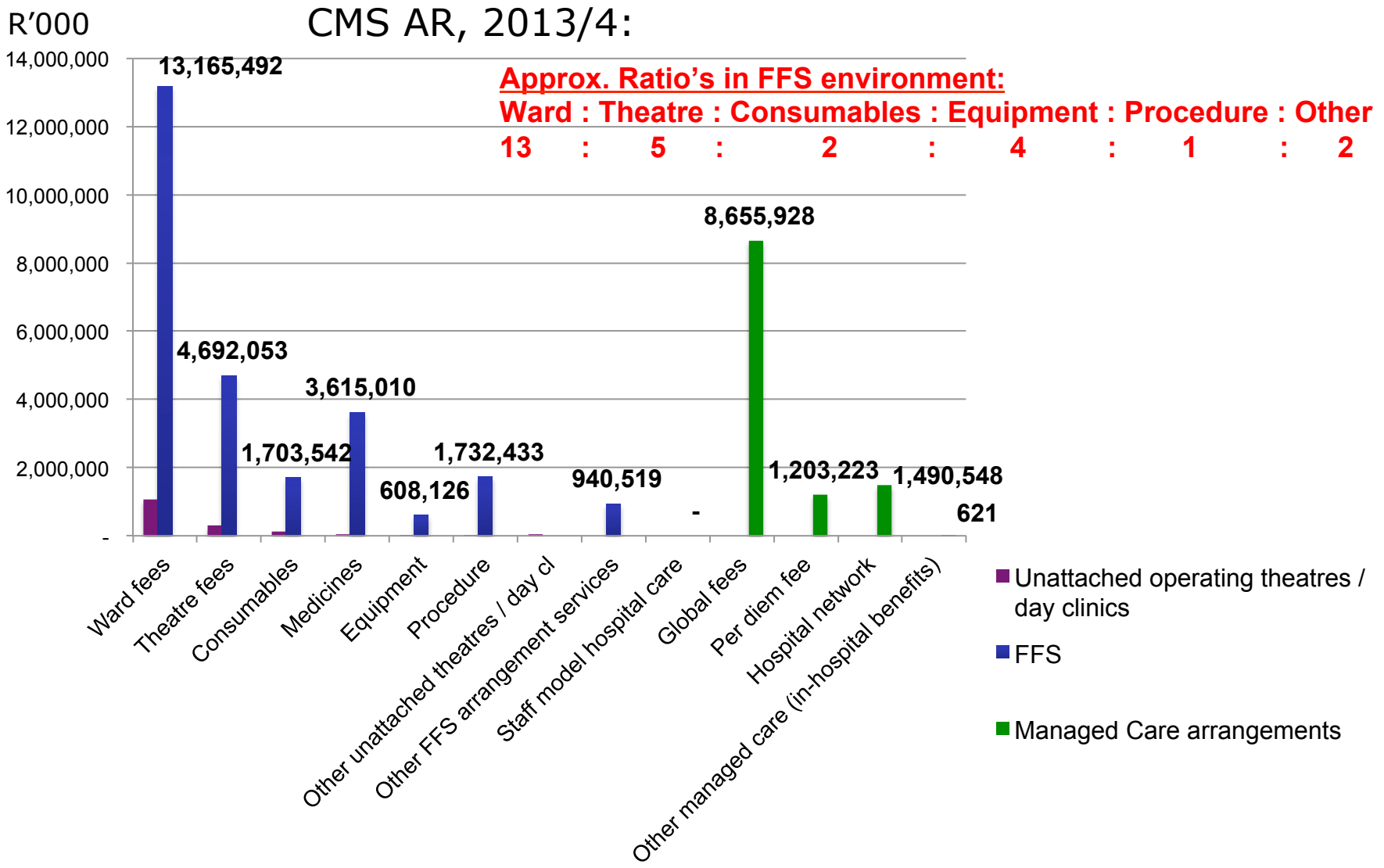
(no longer provided in CMS AR)



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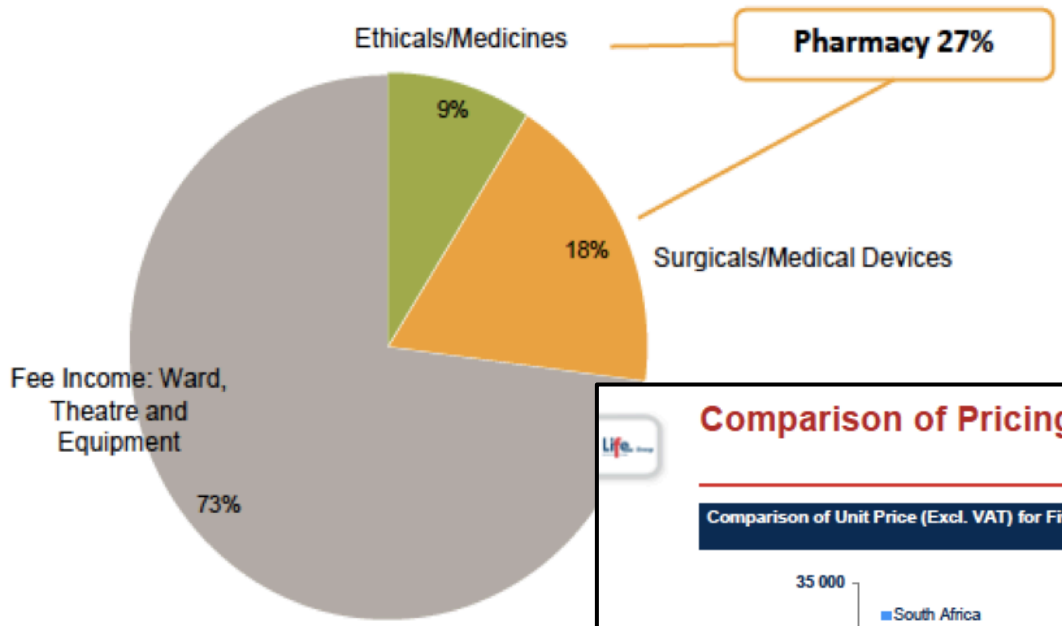
Health Market Inquiry (HMI)

“So, who is this Peter?”

…

“and who are the Departments of Silly Questions?”

OVERVIEW OF A TYPICAL HOSPITAL ACCOUNT



Source: Company information

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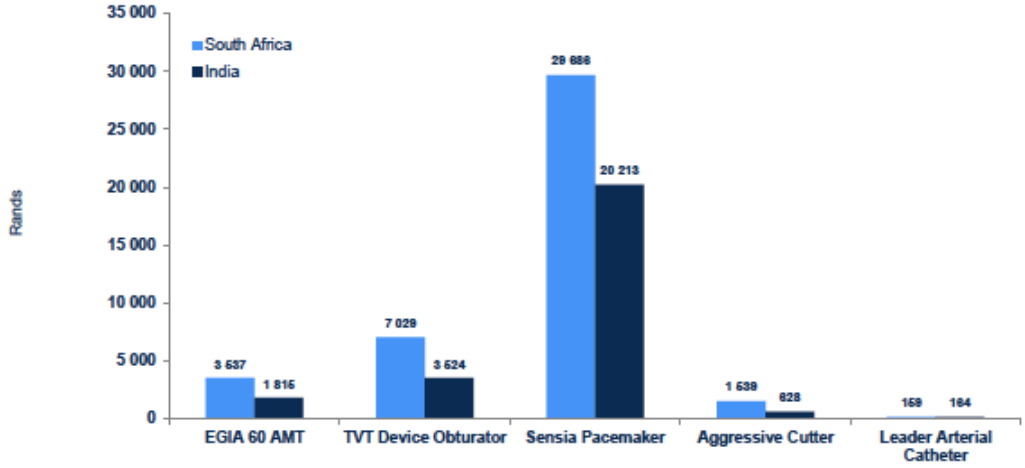
HMI: Mediclinic (left) and Life (bottom) on medical devices

Comparison of Pricing of Surgicals Between SA and India

Comparison of Unit Price (Excl. VAT) for Five High Utilisation Surgicals in Life Healthcare in India and South Africa as at July 2013[1]



	EGIA 60 AMT	TVT Device Obturator	Sensia Pacemaker	Aggressive Cutter	Leader Arterial Catheter
India Price as % of SA Price	51%	50%	68%	41%	103%

Notes[1] ZAR/INR exchange rate of 0.165 utilised for this analysis

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Ok, so what will the law (Acts 72 of 2008 and Act 14 of 2015) do?

Licensing

- Device importers, manufacturers and distributors* to apply for licences under existing s22C of Medicines Act
- Existing s22C(1)(b):
  - issue to a manufacturer, **wholesaler** or distributor of a medicine or medical device a licence to manufacture, import or export, act as a wholesaler of or distribute, as the case may be, such medicine or **medical device**

* Note: Distributors have a different meaning on devices than to medicines; two local co's may distribute for example a device of multinational co X.

Challenge…

- It is understood that wholesalers can rely on their pharmaceutical licences, but no formal section 36 exemption (?yet)

- Engineers who repair and maintain devices would also need a section 22C licence

Registration

- Devices will be called up and then be subject to registration
- Challenge: what happens to products in categories not yet called up, but brought into market for first time after device amendments are in force and effect? (cf CAMS)
- Challenge: What happens to devices currently registered as medicine – process of transfer to device register? Re-evaluation?

Commercial matters

- Devices will NOT be subjected to s22G (price regulation: SEP & fee system)

- Challenge: What happens to device currently registered as medicines and currently subject to price regulation?

Commercial deals

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- Section 18A: No bonus, rebate or incentive scheme *(unless declared acceptable - MoH)*
- Section 18B: No sampling, unless for exhibition or appraisal purposes *(regs needed)*
- Section 18C: Marketing Codes

Agreements with device co's must consider this law change being implemented...

- Challenge:
  - Product placement in facilities? (capex, etc.)
  - Free goods (e.g. glucometer free + strips sold, competitions)?
  - Differential pricing and discounts? (e.g. implants, stents, sutures, etc.)

Commercial deals (continued)

- Challenge:

From when will the prohibitions as per sections 18A and 18B be effective? Only AFTER call-up and AFTER registration, or immediately once amendments Act come into effect? *(same challenge as with CAMS now)*

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In conclusion….

- Greater emphasis on technology &
  - Its cost & value (performance) (HTA),
  - Way in which it is adopted (“when last where you in Chicago for training doctor?”),
  - Protocols / EBM, quality

- Some challenges ahead on implementation of basic legal framework for registration (safety, quality, performance)
- Uncertainty as to commercial deals…

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