

Tanya Vogt
SAMED Executive Officer

Update on SA regulatory requirements for medical devices and IVDs

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2018
—
The EGG
BRUSSELS



A MedTech Europe event

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bringing HealthTech stakeholders together

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Timeline of key events

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Regulation of Medical Devices -Timeline of Key Events

9 Dec 2016	Medical Device/IVD Regulations published under Act 101 Medicines and Related Substances Control Act
24 Feb 2017	Manufacturer / Distributor / Importer / Exporter / Wholesaler Licensing announcement appeared in Gazette
1 Jun 2017	Commencement of Act 72 of 2008 (SAHPRA) – regulations will have to be rewritten
24 Aug 2017	All medical device establishments (manufacturers, importers, distributors) required proof of application for an establishment license
9 Oct 2017	South African Health Products Regulatory Authority Board membership announced
1 Dec 2017	Request for comment on the general regulations relating to bonusing, 3 month comment period
29 Dec 2017	Announcement of Exemption of medical devices and IVDs from 18A and 18B (sampling) for 1 year appeared in Gazette
24 Feb 2018	All wholesalers who buy and sell on medical devices require proof of application for a medical device wholesaler's license
Ongoing	Various Guidelines : Classification, Adverse Events, Quality Manual, Essential Principles of Safety and Performance, Borderline products, etc
?	Amended MD/IVD regulations to align with amended Act

MD/IVD Regs: challenges / impact

- Sub sites / branch licences
- AR at each site
- Advertising of Class C and D MD
- Borderline medical devices – request for designation
- Quality management system: ISO 13485?
- Technical dossier format (RPS vs STED)
- Readiness of conformity assessment bodies

18A draft regulations

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Intended to:

- support the attainment of **affordable** medicines, medical devices and IVD's and to give effect to the **prohibition** of activities which have the effect of **undermining** the **transparent pricing** system of medicines, medical devices and IVDs and more specifically the activities as envisaged in regulation 18A(1), namely the supply of medicine, medical devices and IVDs according to a **bonus** system, **rebate** system or any other **incentive** scheme.

Prohibited activities

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Prohibited activities

a) a discount;

include but not limited to -

- volume or 'bulk purchase' discounts;
- bonus deals in terms of which additional units of the same, related or unrelated medicines, medical devices or IVDs are supplied to customers below the published price or free of charge;
- settlement discounts and rebates, including payments made to customers after the date of sale for timeous payment of accounts or cash payment for achieving sales targets, or for any other reason;

b) payment for marketing, promotion, and advertising;

c) fees for shelf space;

d) data fees and registry fees but excludes the purchase of health informatics supplied by an independent entity, which entity has no association with a customer and where such data is unrelated to the supply of a medicine, medical device or IVD; and also excludes fees payable for registered clinical trials;

e) loyalty fees or similar fees;

f) directors' fees or shareholder fees, honoraria and similar compensation paid to a customer, excluding a fee, honorarium or compensation which is for a legitimate educational activity and at fair value;

g) entertainment costs, meals and disbursements including **congress and conference attendance in excess** of acceptable practices of any marketing **code** approved and or endorsed by the regulator;

- h) payment or contribution by a supplier towards any recurring expenditure of a customer which includes salaries or any subsidy of staff costs of personnel or contractors of a customer;
- i) free services rendered by suppliers or their agents to customers which has the effect of (h) above;
- j) the placement or the provision of any equipment, medicine, medical device or IVDs by suppliers or their agents at a reduced cost, nominal cost or for free to customers whether directly or indirectly, related to or unrelated, to the supply of a medicine, medical device or IVD and includes consignment stock and loan sets;
- k) unjustified credit payments which have the effect of an inducement;
- l) formulary and protocol listing payments to any customer or any person who is able to influence such a listing

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Penalties

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Penalties

- fined or imprisoned for a period not exceeding 10 years
- when an offence has been committed, the fine or imprisonment applies to all parties involved in such an activity
- amount of the fine will be determined having regard to the nature, duration and extent of the contravention
- maximum penalty of 10% of the supplier's turnover in its most recent financial year may be imposed