THE NEW MEDICAL DEVICE REGULATIONS AND GUIDELINES

An Industry Perspective

4 October 2018

Avanthi Govender Bester

SAMED

south african medical technology industry association

advancing innovation responsibly

WHO IS SAMED AND WHAT DO WE DO?

Voice of Medtech Industry in SA

Committed to ensuring a **sustainable** medical technology industry that enhances **patient access** to **innovative solutions**

Established 1985, founding members were local manufacturers

Give our members a collective, objective and credible platform to engage with all stakeholders

Members must comply with Medical Device Code of Ethical Marketing and Business Practice

190 member companies, 4 associations, 16 associate members

SAMED
south african medical technology industry association
advancing innovation responsibly

HALLMARKS OF MEDTECH INDUSTRY

MEDICAL TECHNOLOGIES	MEDICINES
Over 80% small and medium sized enterprises	Very large multi-national companies dominate
Few “generic” devices	Significant “generics” industry
Invented and designed; often with involvement of physician users	Discovered in lab-based research processes
Designed to perform specific functions	Development by discovery and trial
Heterogeneous group; range from tongue depressors to artificial hearts	Tend to differ only in molecular structure, active site, and mode of application

SAMED
south african medical technology industry association
advancing innovation responsibly

HALLMARKS OF THE MEDTECH INDUSTY

MEDICAL TECHNOLOGIES	MEDICINES
Technologies, forms, and modes of action very diverse	Usually in forms of pills, solutions, aerosols, or ointments
Tend to require significant user interaction	Generally little user interaction
Sales channels differ based on product; wholesalers not generally involved	Typically involve wholesalers
Large investments in manufacturing, distribution, and user training/education	Lower manufacturing and distribution costs, and little or no training and clinician support

HALLMARKS OF MEDTECH INDUSTRY

MEDICAL TECHNOLOGIES	MEDICINES
Mfr. technical training and support; service and repair	Most cases little or no service or maintenance
Device malfunction	Drug interactions
User error	Wrong drug or dose
Adverse events most often local in nature	Adverse events may be widespread
Regulatory approval on basis of safety and performance	Regulatory approval on basis of safety and efficacy

HALLMARKS OF MEDTECH INDUSTRY

MEDICAL TECHNOLOGIES	MEDICINES
Short market life (~ 18-24 months)	Long market life
Short investment recovery period; little patent linkage possible; data exclusivity is important	Intensive patent protection, including data exclusivity and patent linkage, needed due to long product life cycle and long investment recovery period
Majority of new products bring added functions and clinical value through incremental improvement	Usually large step innovation
Continuous and rapid innovation and iterative improvements based on new science, new technology, and new materials	Extensive R&D of a specific molecule; many years for new drug to enter product pipeline

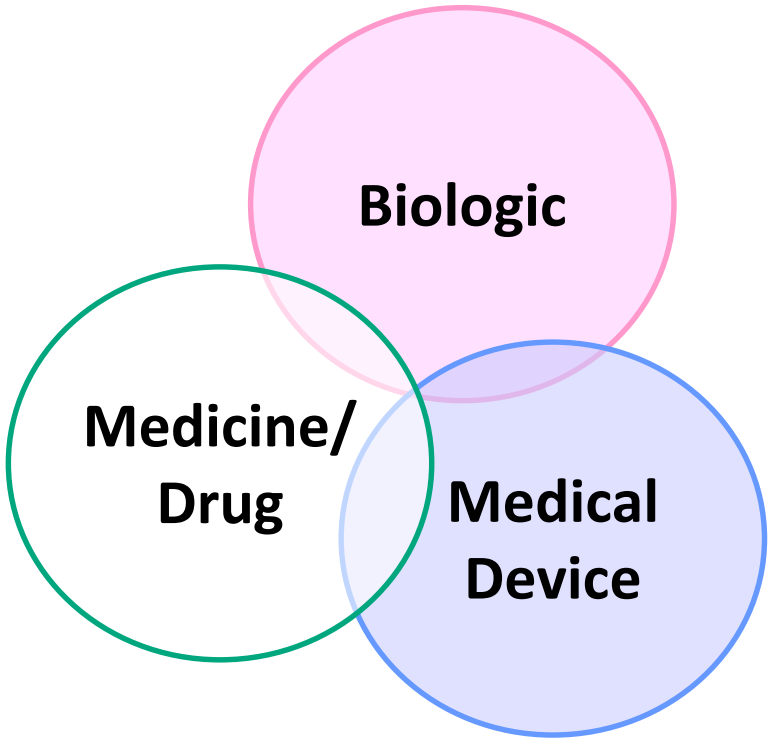
SAMED
south african medical technology industry association
advancing innovation responsibly

Diversity of medical devices

Source: US FDA CDRH 2005 Strategic Plan (modified)

SAMED
south african medical technology industry association
advancing innovation responsibly

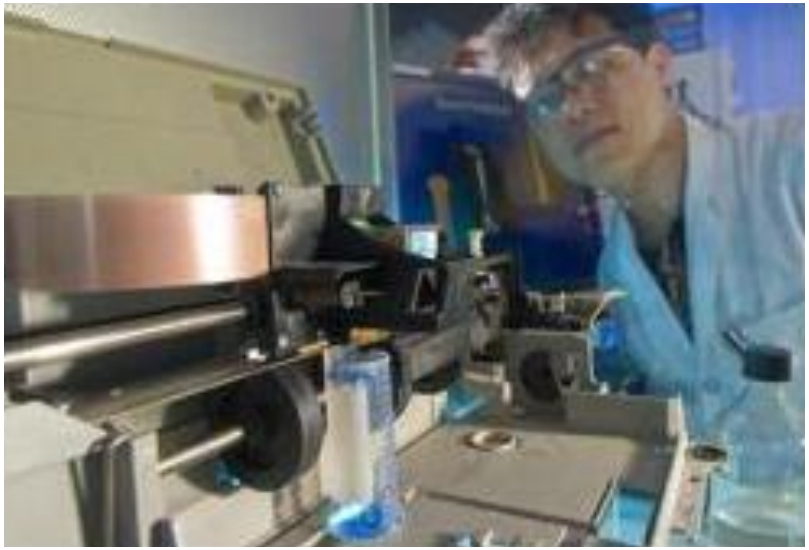
TECHNOLOGY CHANGES AND REGULATIONS



POSSIBLE OVERLAPS WITH OTHER REGULATED SECTORS

TECHNOLOGY CHANGES AND REGULATIONS

Is a printer a medical device?

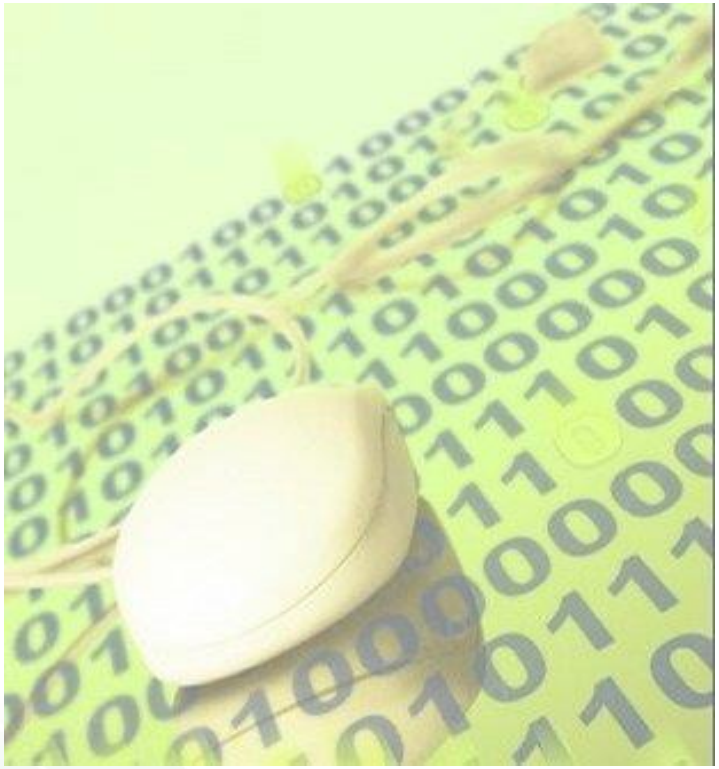


WINSTON-SALEM, North Carolina (Reuters) –
"Inspired by a standard office inkjet printer, U.S. researchers have rigged up a device that can spray skin cells directly onto burn victims, quickly protecting and healing their wounds as an alternative to skin grafts …"

Source: National Post (Canada), Reuters; 7 April 2010

TECHNOLOGY CHANGES AND REGULATIONS

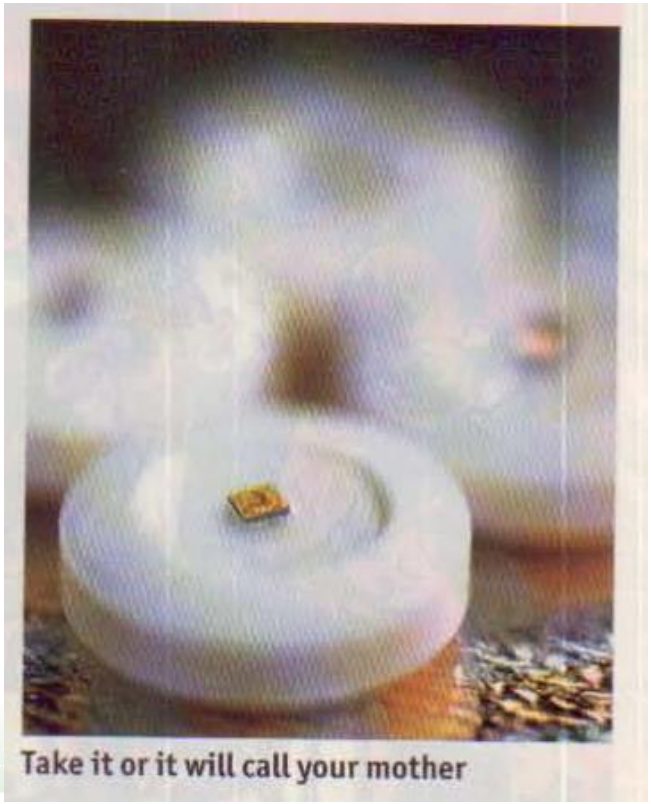
Is computer software a medical device?



Source: Google Images

TECHNOLOGY CHANGES AND REGULATIONS

Is a “smart pill” a medical device?



Pill contains edible communications micro-chip to allow monitoring of patient compliance and/or for adverse effects

Source: The Economist; Jan. 16, 2010

TECHNOLOGY CHANGES AND REGULATIONS

Is a “bionic eye” a medical device?

Source: Agence France Press; 30 March 2010

The device, part of which is surgically implanted in the eye, is designed for patients suffering from degenerative vision loss caused by the genetic condition retinitis pigmentosa or age-related macular degeneration.

It consists of a miniature camera, mounted on glasses, that captures images and sends them to a processor the wearer keeps in their pocket. The processor then transmits a signal wirelessly to a unit implanted in the eye which will directly stimulate surviving neurons in the retina, signalling an image to the brain.

TECHNOLOGY CHANGES AND REGULATIONS

Is a bone adhesive of biological origin a medical device?

Glue bones

Biomedicine: An adhesive secreted by a marine worm inspires a promising new treatment for compound fractures of human bones

Source: The Economist Technology Quarterly: December 13, 2009

BACKGROUND: GLOBAL STATUS

- Medical devices are being recognised as a separate and distinct category of regulation
- Matured regulatory authorities:
  - FDA, Japan and Health Canada stable transparency organizations on decision making affecting medical devices;
  - European Union (EU) - 2016 significant changes to their regulation of medical devices
  - Australia - reforms to allow for approval of work done by comparative international regulatory authorities
  - Brazil, China and Russia - actively working to implement systems
- Developing countries
  - Developing regulatory controls

WHAT HAS INDUSTRY BEEN BUSY WITH?

01

Licensing as a manufacturer, distributor or wholesaler

02

Appointment of an authorized representative

03

Implementation and accreditation of a Quality Management System

04

Product Listing and Product Registration

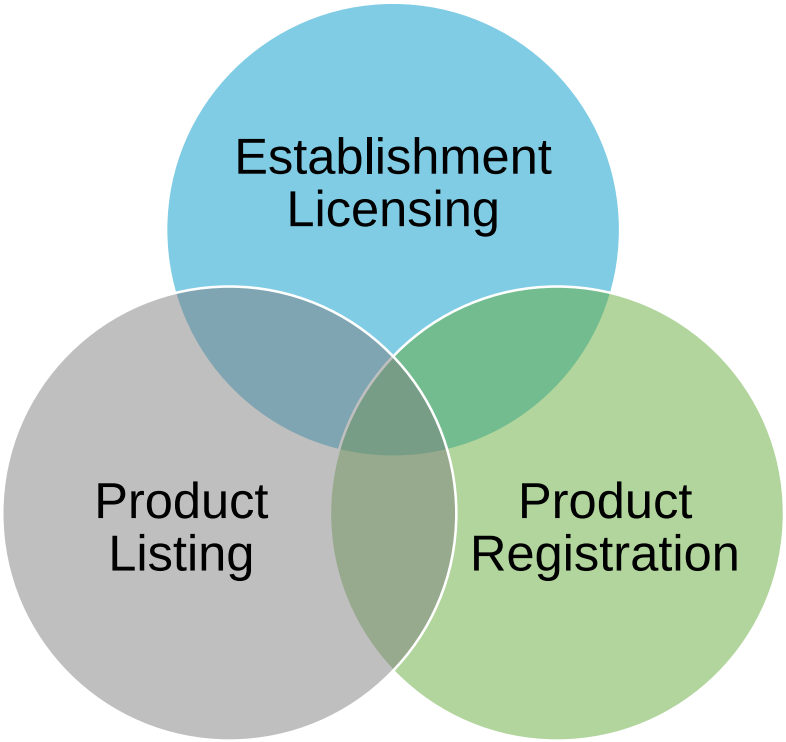
SAMED
south african medical technology industry association
advancing innovation responsibly

STATUS AND PROGRESS TO DATE:

- License applications submitted
- Licenses received – mostly
- Vigilance reports submitted
- Clinical trial applications submitted

SAMED
south african medical technology industry association
advancing innovation responsibly

INDUSTRY PERSPECTIVE



ESTABLISHMENT LICENSING

- Definition of a manufacturer, distributor and wholesaler
- Appointment of the Authorised Representative
- Quality Management System
- Fees
- Contracts and Quality Agreements

SAMED
south african medical technology industry association
advancing innovation responsibly

PRODUCT LISTING

- IVD and non-IVD products
- Classification
- GMDN code
- Veterinary Products
- Recognition countries
- High-risk product requirements

PRODUCT REGISTRATION

- Timing
- Risk-based approach
- Technical dossier requirements
- Labeling requirements
- Fees

OTHER

01

Inspectorate – expertise and relevance

02

Licensing and Administrative Functions

03

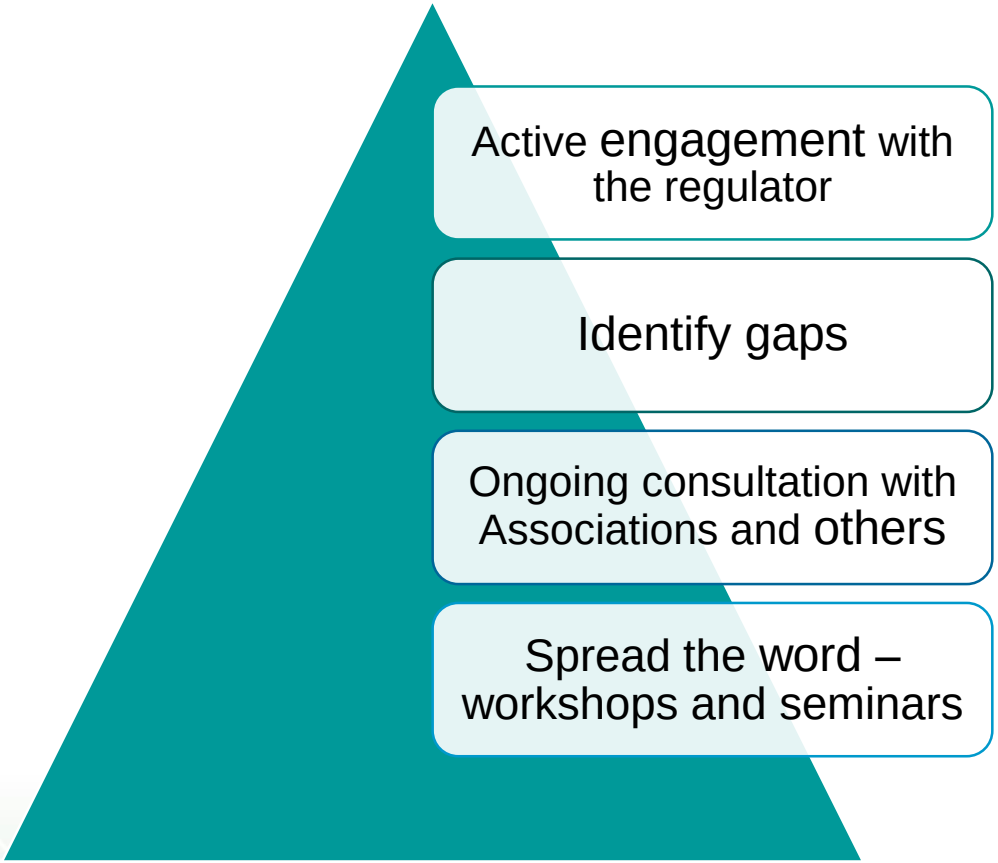
Guidelines

04

Transparency and Consultation

SAMED
south african medical technology industry association
advancing innovation responsibly

HOW CAN INDUSTRY SUPPORT?



IN CLOSING…

Acknowledge

- Estimated 2 million different kinds of Medical Devices

Common Goal

- Appropriate, affordable medical devices that are responsive to the needs of the patient
- Safety, quality and performance

SAMED
south african medical technology industry association
advancing innovation responsibly