ADVANCING INNOVATION RESPONSIBLY

CSSD CONFERENCE: 30 May 2019

Update on The Medical Device Code of Ethical Marketing and Business Practice

Tanya Vogt
SAMED Executive Officer

SAMED
south african medical technology industry association
advancing innovation responsibly

ABOUT SAMED

South African Medical Technology Industry Association

Non-profit established in 1985

197+ member companies of diverse profile and size

SAMED
south african medical technology industry association
advancing innovation responsibly

SAMED VISION

To develop a sustainable medical technology industry that enhances patient access to innovative solutions

SAMED MISSION

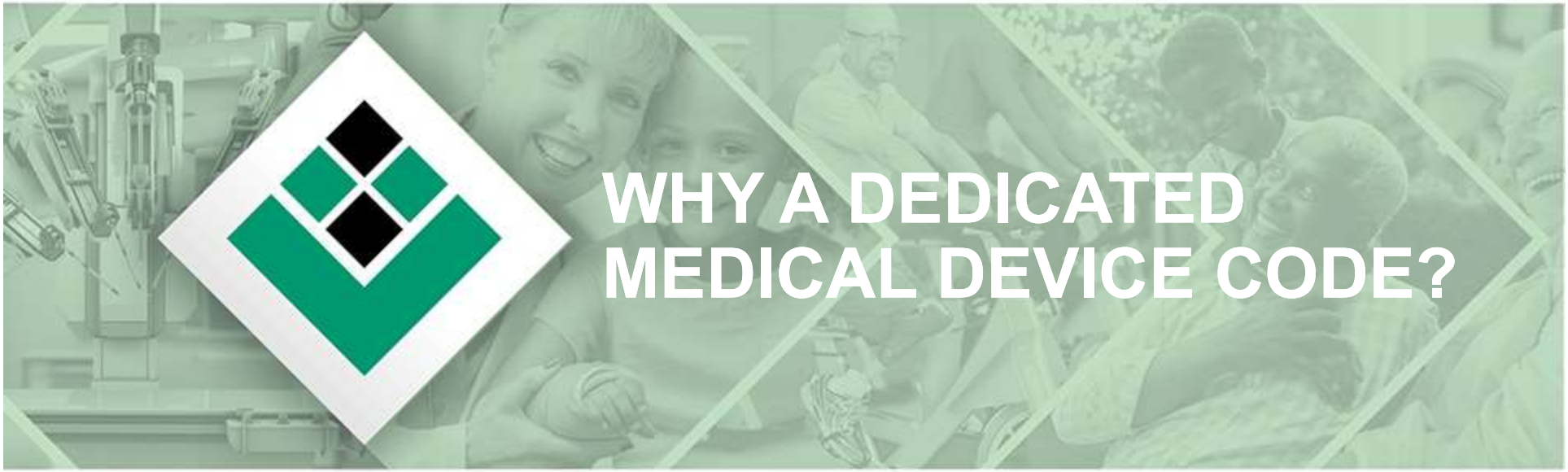
SAMED is committed to providing the industry with a collective, objective and credible platform for engaging with all stakeholders

SAMED
south african medical technology industry association
advancing innovation responsibly

SAMED GOAL & OBJECTIVES

Advance innovation responsibly

- Improve patient care through enhanced patient access to innovative solutions
- Build a sustainable, relevant & representative industry positioned within a healthcare sector that meets the needs of patients
- Contribute to an effective, efficient & harmonised regulatory environment
- Ensure ethical and effective procurement & payment models within the framework of universal health coverage



WHY A DEDICATED MEDICAL DEVICE CODE?

SAMED
south african medical technology industry association
advancing innovation responsibly

IN HEALTHCARE REGULATION

IT'S ALL ABOUT THE PATIENT

- Expansion of health sector regulators since 1994
  - Council for Medical Schemes
  - Office of Health Standards Compliance
  - SA Health Products Regulatory Authority
  - SA Research Ethics Council
- In these, as in older regulatory bodies, the aim is to safeguard the patient and improve healthcare
- Industry self-regulation strengthened through dedicated Code of Ethical Marketing & Business Practice
- By adopting this approach we are demonstrating to government that we are **serious** about doing away with **perceived perverse practices** in the hope that government will allow us to **self-regulate**

GLOBAL WINDS OF CHANGE IMPACTING INDUSTRY'S INTERACTION WITH HCPs

- Ethical conduct of government and business organisations under close scrutiny
- Call for greater transparency, disclosure
- Increased litigation and fines of medical device companies

Bribery on Two Continents: Olympus Corp., to Pay $646 Million Settlement

Patient Safety Monitor Insider

March 2, 2016

On March 1, the Department of Justice (DOJ) charged Olympus Corp. with paying millions of dollars in kickbacks to hospitals and doctors to buy its products. The company, which owns 85% of the U.S. endoscope market, has agreed to pay $646 million to resolve the criminal charges and civil charges brought against it. The sum is the largest total amount paid in U.S. history for violations involving the Anti-Kickback Statute by a medical device company.

?Olympus Corp. of the Americas? and its subsidiaries? greed-fueled kickback scheme threatened the impartiality of medical decision-making and the financial integrity of Medicare and Medicaid,? said Special Agent in Charge Scott J. Lampert of the U.S. Department of Health and Human Services in a statement.

The DOJ says that by using kickbacks, Olympus? U.S. division (OCA) made over $600 million in sales and $230 million in profits. The company admits to the charges, which include:

- Holding up a $50,000 research grant until a hospital signed a deal to purchase Olympus equipment
- Giving a doctor with a major role in a New York medical center?s buying decisions free use of $400,000 in equipment for his private practice.

REF: PATIENT SAFETY MONITOR

- The DOJ says that by using kickbacks, Olympus U.S. division (OCA) made over $600 million in sales and $230 million in profits. The company admits to the charges, which include:
- Holding up a $50,000 research grant until a hospital signed a deal to purchase Olympus equipment
- Giving a doctor with a major role in a New York medical center buying decisions free use of $400,000 in equipment for his private practice.
- Paying off doctors with hot air balloon rides, winery tours, spa treatments, lavish meals and rounds of golf at an Olympus sponsored forum.
- Paying for a trip for three doctors to travel to Japan in 2007 as a quid pro quo for their hospitals decision to switch from a competitor to Olympus.
- Giving a hospital a $5,000 grant to facilitate a $750,000 sale.
- Giving a week-long, paid vacation in Japan to the physician president of a professional organization and his spouse for three years in a row. The president was also paid a $10,000 honorarium to give a single lecture during each trip.

Device Firms Would Have To Rep

https://medtech.pharmaintelligence.informa.com/MT124943/Device-Firms-Would-Have-To-Report-Value-Of-Device-Samples-For-Patient-Use-Under-STAR-Act

MENU

Device Firms Would Have To Report Value Of Device Samples For Patient Use Under STAR Act

12 Apr 2019 | **NEWS**

by Sue Darcey

sue.darcey@informa.com

Executive Summary

An amendment to the Physician Payment Sunshine Act approved by a House Committee on April 9 would require device manufacturers to report the value of any samples given to physicians, a requirement that could include some free samples a doctor uses when educating his patients on device use.

Related Content

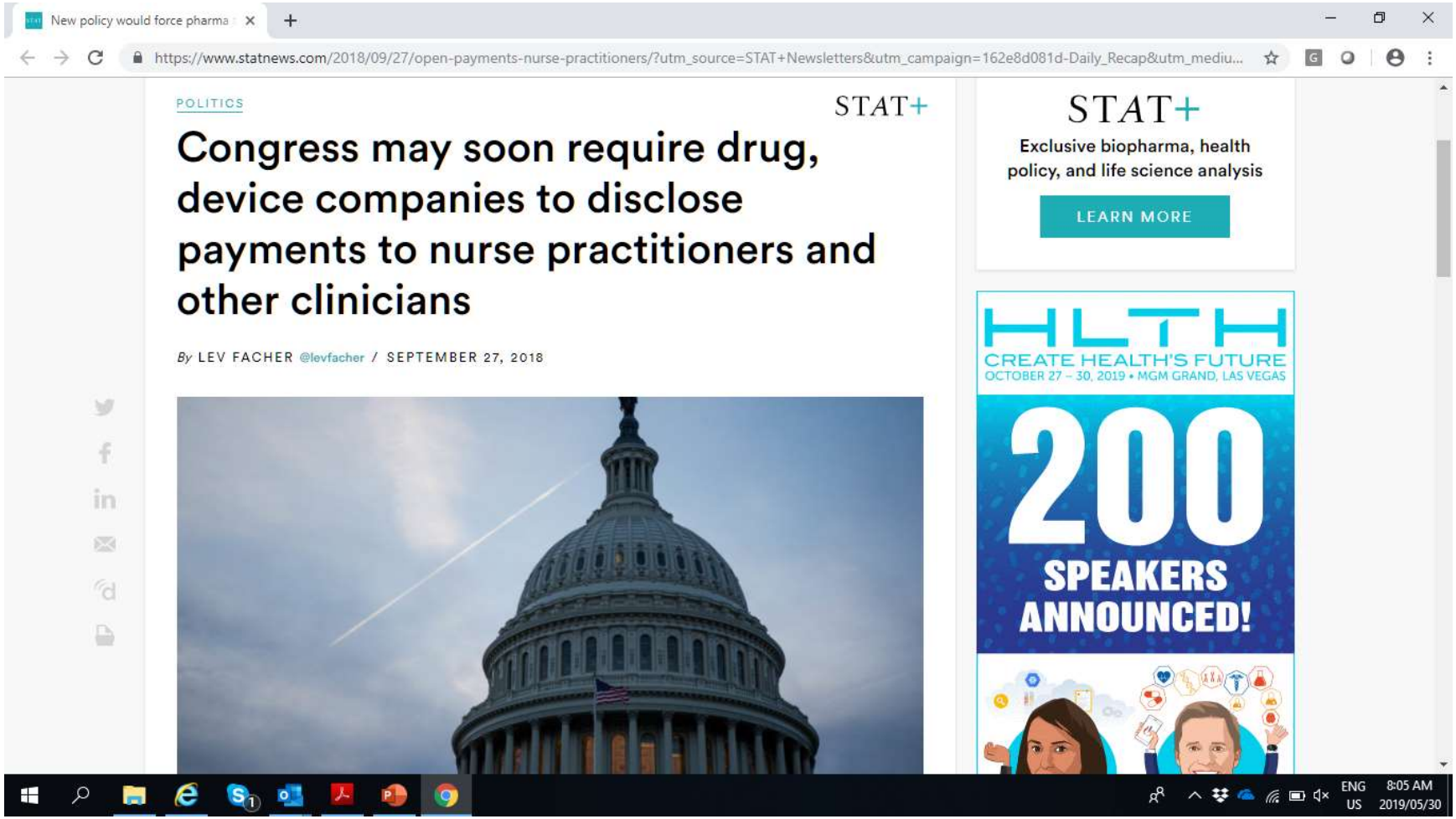
MEDTECH INSIGHT

Lawmakers Question Effectiveness Of Free Sample Reporting

feedback

ENG US 8:01 AM 2019/05/30

SAMED
south african medical technology industry association
advancing innovation responsibly



SAMED
south african medical technology industry association
advancing innovation responsibly

GLOBAL WINDS OF CHANGE IMPACTING INDUSTRY'S INTERACTION WITH HCPs

- **Locally**

HPCSA Booklet 11, SA Anti Corruption Act, 18A Draft Regs etc. **Prohibited:** 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

- **Internationally**

Advamed and MedTech Code, FCPA, Sunshine Act, UK Anti Bribery Act

- **Align with international best practice**
- **Global compliance forum May 2019: call for harmonisation**

UNIQUE INTERACTIONS WITH HCPs

- Close working relationships with HCPs are lifeblood of devices industry
- Without doubt, these relationships are indispensable to good patient care and progressive practice
- Extent of interdependence puts devices industry in special league
- But strong interdependence breeds possible risk of manipulation or collusion that has negative impact on patient
- Clear rules and the guidance (and possible sanction) of peers and competitors are essential safeguards for industry, HCPs and patients

MULTIPLE PLATFORMS FOR UNIQUE INTERACTIONS

Platform	Devices	Pharmaceuticals
Advancement of products	Developed in collaboration with HCPs	R&D in labs by scientists
Product life-cycle	Short (2-4 years), ongoing evolution	Long, unchanging compound
Clinical evaluation & RCT standardisation	Difficult to blind and standardise, no placebo, multiple users, training long & ongoing, influenced by settings / users	Easy to blind and standardise, usually one end-user, shorter training, less dependent on setting / user
Safe & effective use	Outcomes depend critically on skills/experience of user, requiring intensive & ongoing training / education	Outcomes less dependent on skill / experience of user
Additional support provision	Service & maintenance for many high-tech devices	Mostly, little or no training, service or maintenance

CODE DRAWS THE ETHICAL LINE

Fundamental principle and purpose of the Code:

- **The principle of image and perception**
  - Medtech industry should at all times, consider the image and perception projected to the public when interacting with HCPs

- Companies may not offer any inducement to any HCP or other customer in order to sell, lease, recommend, or arrange for the sale or lease of their products

- Essence of Code is to draw the line between essential value of key practices and distortion of practices for unethical gain

- Code gives clear guidance on where the line lies in each set of circumstances

WHO DOES THE CODE APPLY TO

- **SAMED members and MedTech Industry (signatories)**
- **"Healthcare professional (HCP)"** meaning any individual (with a clinical or non-clinical role)

  Government official, or employee or representative of a government agency or other public or private sector organisation; including but not limited to physicians, nurses, technicians, laboratory scientists, researchers, research co-ordinators or procurement professionals that in the course of their professional activities may directly or indirectly purchase, lease, recommend, administer, use, supply, procure or determine the purchase or lease of, or who may prescribe medical technologies or related services

Snapshot of The Code

Part 1: Interactions with healthcare professionals

- Promotional items, competitions & charitable donations
- Demo products, samples, loaned & placed devices
- Consultant fees & royalties
- Patient registries
- False claims to medical schemes
- Conduct of healthcare representatives
- Company & third-party arranged educational events
- Advertising of medical devices

Part 2: Dealing with infringements

- SAMED-selected Ethics Committee
- Complaint procedure
- Independent investigation
- Conduct of hearings
- Sanctions

Part 3: Questions and answers

Part 4: Complaint form

SAMED
south african medical technology industry association
advancing innovation responsibly

INDUCEMENT?

SAMED
south african medical technology industry association
advancing innovation responsibly

DEMONSTRATION PRODUCTS AND SAMPLES

- May provide examples of products in the form of mock-ups (such as unsterilised single use products) that are used for HCPs and patient awareness, education and training
- Not intended for clinical use, to be sold or transferred
- May provide a reasonable number of samples at no charge over certain period to allow HCP/patient to familiarise themselves with the product

APPROACH TO ENTERTAINMENT

- **NO** entertainment, **NO** gifts of any kind, including those of cultural or religious significance or related to national events
  Research in social science demonstrates that the recipient of a gift feels a sense of obligation that is often subconscious

PROMOTIONAL AIDS & ITEMS OF MEDICAL UTILITY

Promotional items must be:

- Branded, inexpensive, of modest intrinsic value within maximum prescribed by national laws, regulations, industry and professional codes
- Related to HCP's practice and for benefit of patients
- Medical utility and/or scientific value
- Not for personal use by HCP

- **Unacceptable**
  - Entertainment CDs/DVDs, electronic items for entertainment, tickets to sporting events or other forms of entertainment
  - Cash or cash equivalents (eg vouchers)
  - Food, alcohol and items which are primarily for use in the home, car, gym
  - Gifts of any kind, including those of cultural/religious significance or related to national events
- **Acceptable**
  - Scientific reference books, journals, anatomical models intended for teaching or patient benefit
  - Stationery items, calendars, diaries, computer accessories for business use
  - Clinical items such as wipes, nail brushes, surgical gloves and tourniquets

APPROACH TO SPONSORSHIP

- Direct sponsorship of HCPs to third party organised educational events **prohibited since 1 January 2018**

SAMED
south african medical technology industry association
advancing innovation responsibly

INDIRECT SPONSORSHIP

- Our industry is **still fully** committed to supporting medical education.

- We will now do this **at arms' length** through **independent third-parties**.

- The independent third party **will decide** which HCPs receive the funding, aligned with **pre-determined selection** criteria.

INDIRECT SPONSORSHIP: INDUSTRY AND THIRD PARTY GUIDANCE DOCUMENT

- SAMED has developed a set of **guidance tools to** help you and third parties to manage this process. These include:

  - Criteria for Companies' support for third-party organised educational events
  - Guidance on Third Party Selection of Recipients of Grants
  - An Educational Grant Agreement Template
  - A Grant Request Application Template Form
  - Guidance on Vetting Educational Conference Organisers
  - Frequently Asked Questions and Answers

Click here for: Guidance on indirect sponsorship

SAMED
south african medical technology industry association
advancing innovation responsibly

?

DO YOU THINK IT IS ETHICAL FOR INDUSTRY TO PAY FOR HCPs TO ATTEND COMPANY AND THIRD-PARTY ARRANGED EDUCATIONAL EVENTS?

SAMED
south african medical technology industry association
advancing innovation responsibly

HPCSA BOOKLET 11: GUIDELINES ON OVERSERVICING, PERVERSE INCENTIVES AND RELATED MATTERS

3.13 CONTINUING PROFESSIONAL DEVELOPMENT

- 3.13.4 Funding

Funds for continuing professional development activities should preferably be in the form of an **educational grant payable to the healthcare provider organisation** arranging the activity.

- 3.13.5 Travel, lodging and other expenses with regard to the attendance of CPD events

No travel or lodging costs or other expenses should be paid by the industry **directly** to the individual healthcare practitioners to attend a CPD event. However, **indirect funding** or scholarship of CPD events may be permissible in instances where, such sponsorships are paid to the organisers of the CPD events who in turn will identify, through a transparent selection process, deserving candidates based on such factors as historically disadvantaged individual's status, gender, geographical location….. …

HPCSA BOOKLET 11: GUIDELINES ON OVERSERVICING, PERVERSE INCENTIVES AND RELATED MATTERS

- 3.13.6 Travel, lodging and other expenses with regard to the attendance of international Conferences

3.13.6.1 ……It will, therefore, be permissible for companies to sponsor delegates to attend international conferences, either directly **or through professional associations or societies, with the proviso that a fair and transparent process** should be followed in the election and sponsoring of delegates to attend such events, especially with regard to the attendance of such conferences by young and upcoming healthcare professionals and educators…….

- 3.13.7 Distinction between education, training and product promotion

Healthcare practitioners cannot earn CEUs for attending product launches or other product promotion events. **No travel, lodging or other expenses of healthcare practitioners should be paid for attendance at product promotion events or product launches. However, modest meals may be provided.**

CAN I GO DIRECTLY TO A COMPANY AND ASK FOR SPONSORSHIP TO A CONFERENCE?

SAMED
south african medical technology industry association
advancing innovation responsibly

INDIRECT SPONSORSHIP

- No, you should approach your professional society and/or the conference organizer. However you should you always get permission from your manager.

?

A HOSPITAL HAS SUBMITTED A GRANT REQUEST TO SUPPORT THE ATTENDANCE OF ONE OF THEIR EMPLOYEES TO A THIRD PARTY ARRANGED EDUCATIONAL EVENT. THE HOSPITAL DOES NOT HAVE THE FACILITIES TO ARRANGE TRAVEL. CAN A COMPANY ARRANGE THE TRAVEL ON BEHALF OF THE HOSPITAL?

INDIRECT SPONSORSHIP

- No. Companies are not permitted to make logistics arrangements for individual HCPs attending or speaking at third party educational events. They can provide financial support to the hospital but the hospital must make all arrangements themselves.

?

A COMPANY HAS OFFERED YOU FREE SAMPLES FOR THE NEXT 5 MONTHS TO TRY OUT A NEW MEDICAL DEVICE? IS THIS ACCEPTABLE?

SAMED
south african medical technology industry association
advancing innovation responsibly

SAMPLES

- Company may provide a **reasonable number of samples at no charge** to allow HCPs and/or HCOs to familiarise themselves with the products and/or related services, to acquire experience in dealing with them safely and effectively in clinical use and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future
- For single-use product samples, the quantity provided for purposes of familiarisation must not exceed the amount reasonably necessary for the HCPs/HCOs to acquire adequate experience in dealing with the products
- For multiple-use product samples, the specific length of time necessary for an HCP to familiarise him/herself with the product will depend on the frequency of anticipated use; the duration of required training; the number of HCPs who will need to acquire experience in dealing with the product; and similar considerations

SAMPLES

- Company shall in all cases maintain appropriate records in relation to the provision of demonstration products and/or samples to HCPs and/or HCOs, for example recording proof of delivery for any demonstration products and/or samples provided and receipt of return for multiple-use demonstration products and/or samples
- Shall clearly record in the member company's records as well as clearly disclose to HCPs and/or HCOs the no-charge basis and other conditions applicable for the supply of such demonstration products and/or samples no later than the time of the supply
- The disclosure to HCPs and HCOs shall be in writing

?

MAY COMPANY REPRESENTATIVES WEAR THEIR COMPANY BRANDED OVERSHOES AND / OR THEATRE CLOTHES INTO THEATRE?
CAN THEY ASSIST THE SURGEON?
DOES THIS IMPACT PROCUREMENT DECISIONS?
HOW?
ARE THERE ANY RISKS INVOLVED?

SAMED
south african medical technology industry association
advancing innovation responsibly

ANSWER

- Yes and no. A company rep may only wear such items if they are appropriate and have been approved by the facility
- Infection control?
- Has the surgeon obtained patient consent?
- Regardless of whether they are a registered nurse or not, a company representative may not touch a patient under any circumstances even if demonstrating / training a product
- What if something goes wrong? Who is liable?
- Has the company rep taken CRICE course? www.crice.co.za
- Is this the right place for company marketing?
- Does a company rep providing assistance influence what medical device is used / procured?

?

WOULD YOU PARTICIPATE IN IMPLEMENTING ENFORCEMENT OF THE CODE? CAN YOU LODGE ANONYMOUS COMPLAINTS?

SAMED
south african medical technology industry association
advancing innovation responsibly

WHAT IS YOUR ROLE?

Get familiar with the Medical Device Code of Ethical & Business Practice

Be on a lookout for possible transgressions, submit complaints and help us implement the Code for benefits of patients, HCPs, entire healthcare system

Earn 2 CPD points for ethics for completing certification course
www.samed/org.za/Codes-of-Practice/aspx

Ask company reps if they have taken CRICE course
www.crice.co.za

SINGLE-USE DEVICES

"single use" in terms of a medical device means one use of a medical device on an individual or IVD on a sample during a single procedure and then the medical device or IVD is disposed of and is not reprocessed and not used again;

"reprocess" means the activity carried out on a used medical device in order to allow its safe re-use including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoration of the technical and functional safety of the used medical device;

Devices labelled "for single use" are designed with the intention by manufacturers that they will not be re-used.

ANSWER

POSITION TAKEN BY SAHPRA

- Medical devices intended by the original manufacturer for single use must be labelled as such.
- Medical devices intended by the original manufacturer for single use may only be used once, may not be reprocessed and must be disposed of after use.
- In the event that the sterility of a sterile medical device intended by the original manufacturer for single use has been compromised and the sterile medical device intended by the original manufacturer for single use, has not been used, the compromised medical device intended by the original manufacturer for single use may not be reprocessed and must be disposed of.
- Medical devices which are intended by the original manufacturer to be reprocessed, using pre-determined and validated procedures to ensure the safe re-use including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoration of the technical and functional safety of the used medical device, may be legally reprocessed. The user of a medical device that is legally permitted to be reprocessed is responsible for adhering to the pre-determined limitations on the number times that the medical device is reprocessed and reused as stipulated by the original equipment manufacturer.
- Reprocessing of any medical device which is intended by the original manufacturer for “single use” is in contravention of Act 101 of 1965.
- The importation of reprocessed single use medical devices, that have been reprocessed in another country and are intended for sale in the Republic of South Africa as a single use medical device is not permitted.

Contact Details

- Jerry Molokwane
  - Acting Director: Inspectorate and Law Enforcement
    - Jerry.Molokwane@sahpra.org.za
- Andrea Keyter
  - Deputy Director: Medical Devices
    - Andrea.Julsing@sahpra.org.za
- Licensing Queries
  - Khanyisile.Nkuku@sahpra.org.za
  - Geena.Leroux@sahpra.org.za
  - Matlapeng.Shabalala@sahpra.org.za

www.sahpra.org.za
012 842 7580 / 7585

Thank You