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Ethical considerations in the South African medical equipment and devices arena

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Abstract

There are presently no regulations regarding the sale and use of medical devices in South Africa apart from electro-medical devices which are regulated by the Directorate of Radiation Control, an agency of the National Department of Health, and combination products, with a medicine component, which are regulated by the Medicines Control Council of South Africa.

It is concerning that in recent years a number of international medical device companies have been implicated, along with health care professionals, in unethical behaviour / business dealings. To this effect, and in the absence of regulations, the South African Medical Device Industry Association (SAMED), a not for profit organization that represents the interests of the medical device industry in South Africa (SA), developed a code of ethical marketing and business practice that reflects the unique and complex interactions between medical device companies and health care professionals. The code draws heavily from international ones; it attempts to address the complexity of medical technology and the importance of having health care professionals understand how to use the technology safely and effectively.

Keywords

code, marketing, perverse, health care professionals

Introduction

There are presently no regulations regarding the sale and use of medical devices in South Africa (SA) apart from for electro-medical devices which are regulated by the Directorate of Radiation Control, an agency of the Department of Health, and combination products with a medicine component, regulated by the Medicines Control Council of South Africa (MCC) [1]. In order to highlight the importance of ethical conduct in the local industry it was deemed necessary to draw extensively on international codes [2, 3]. This article is therefore an amalgam of available international codes which have been adapted for local implementation. The South African Medical Device Industry Association (SAMED) [4] has for many years supported the call to regulate the medical device industry, not only in terms of the quality, safety and purposefulness of devices but also in terms of the interactions between industry and health care professionals (HCPs). In view of the industry's specific terminology it should be noted that many words and phrases of the local code are the same or similar to those published in the literature [2, 3].

For reference sake, a medical device is defined as [5]

...any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

(a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- Investigation, replacement, modification, or support of the anatomy or of a physiological process
- Support or sustaining life
- Control of conception
- Disinfection of medical devices
- Providing for information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body

and

(b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

It is concerning that in recent years, internationally, a number of medical device companies have been implicated along with HCPs in unethical behaviour and/or business dealings. To this effect and in the absence of regulations, SAMED together

with a number of other associations operating in the health products arena, have developed a code (hereafter 'the Code') [6] of ethical marketing and business practice that reflects the unique and complex interactions between medical device companies (hereafter 'Companies') and health care professionals. The Code also attempts to address the complexity of medical technology and the importance of having HCPs understand how to use the technology safely and effectively.

Medical devices are often highly dependent upon 'hands on' HCP interaction from beginning to end – unlike drugs and biologics, which act on the human body by pharmacological, immunological or metabolic means. For example, implantable devices are often placed in the human body to replace or strengthen a body part. Surgical medical devices often serve as extensions of a physician's hands. In other circumstances, medical devices are noninvasive reagents, instrumentation and/or software to aid in the diagnosis, monitoring and treatment decisions made by health care professionals. Many medical devices require technical support during and after deployment.

Interactions with health care professionals

The Code aims to be in line with other applicable policy documents that bind HCPs, such as the *Guidelines and Ethical Rules of Conduct* for practitioners registered

under the Health Professions Act ^[7] and the Health Professions Council of South Africa's (HPCSA) policy on *Undesirable Business Practices* that includes perverse incentives policy ^[8].

From the outset, it is important to emphasize that the Code underpins SAMED's vision, namely: the responsible and ethical advancement of the interests of the medical devices industry within the SA healthcare environment while promoting better patient outcomes. The underpinning maxim of the Code being that SAMED member companies will not offer any inducement to a HCP or other customers in order to sell, lease, recommend, or arrange for the sale or lease of their products.

The Code seeks to provide guidance on the interactions of SAMED with individuals (clinical or non-clinical, including but not limited to, physicians, nurses, technicians and research coordinators) or entities (such as hospitals or group purchasing bodies) that directly or indirectly purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' medical devices.

The scope of beneficial interactions between HCPs and Companies is broad and includes interactions intended to highlight important issues ^[2-4, 6].

- **Promote the advancement of medical technology.** The development of innovative medical devices and the improvement of existing products require collaboration between Companies and HCPs. Innovation and creativity are essential to the development and evolution of medical devices, often occurring outside the facilities of medical device companies. Heart valves, magnetic resonance imaging (MRI) equipment, cardiac rhythm devices, surgical tools, and infusion pumps are just a few examples of the array of complex medical technologies developed through research collaborations and consulting relationships between HCPs and Companies.
- **Safe and effective use of medical technology.** The safe and effective use of sophisticated electronic, *in vitro* diagnostic, surgical, or other medical technology often requires Companies to offer HCPs appropriate instruction, education, training, service and technical support.
- **Research and education.** Compa-

nies' support of *bona fide* medical research, education, and enhancement of professional skills serves patient safety and increases access to new technology.

- **Foster charitable donations and giving.** Companies make monetary and medical technology donations for charitable purposes, such as supporting indigent care, as well as patient and public education. This increases access to, as well as the quality of, care and treatment in patient populations that may not otherwise be reached.

Purpose of the Code

The fundamental purpose of the Code is to promote and encourage, among SAMED member companies, ethical principles and practices. SAMED recognises that a HCP's first duty is to act in the best interests of patients. Companies can serve the interests of patients through beneficial collaborations with HCPs.

To ensure that these collaborative relationships meet high ethical standards they must be conducted with appropriate transparency and in compliance with applicable laws, regulations and government guidance. SAMED recognises the obligation to facilitate ethical interactions between companies and HCPs to ensure that medical decisions are based on the best interests of the patient.

The ethical promotion of medical devices is vital in helping to ensure that HCPs and the public have access to the information they need; that patients have access to the health products they need; that health products are prescribed and used in a manner that provides the maximum healthcare benefit to patients. As such the Code is an essential guide and support for SAMED companies in their business interactions with HCPs. The Code is not a rule book but gives guidance; this guidance springs from chosen ethical values. Such ethical values include:

- an industry that is socially responsible towards not only its customers, but to society at large and patients in particular;
- the desire to promote a spirit of co-operation and shared responsibility among public and private HCPs and providers, which shall include the State, as well as other relevant sectors, within the context of effective, efficient and transparent health care delivery.

In support of this, SAMED has endeavoured to ensure that the Code is circulated to all key stakeholders, namely HCPs, hospitals, government, tender authorities, funders, etc, and that it be accepted as the basis for engagement with these parties.

Key principles

The Code is based on the following key principles:

- **The principle of separation:** Interaction between industry and HCPs must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of companies' products.
- **The principle of transparency:** Interaction between industry and HCPs must be transparent and comply with national and local laws, regulations or professional codes of conduct. In countries where specific provision is not made, companies shall nevertheless maintain appropriate transparency by requiring prior written notification is made to the hospital administration, the HCP's superior or other locally-designated competent authority, fully disclosing the purpose and scope of the interaction.
- **The principle of equivalence:** Where HCPs are engaged by a member to perform a service for or on behalf of a member, the remuneration paid by the member must be commensurate with, and represent a fair market value for, the services performed by the HCP.
- **The principle of documentation:** For interactions between a member and a HCP, such as where services are performed by a HCP for or on behalf of a member, there must be a written agreement setting out, *inter alia*, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the member. The activities envisaged by the agreement must be substantiated and evidenced by activity reports and the like. Adequate documentation such as the agreement, related reports, invoices etc. must be retained by the member to support the need for, and materiality of, the services

as well as the reasonableness of the remuneration paid.

Areas covered by the code

1) Healthcare sales representatives

- Gaining interviews: Healthcare sales representatives must not employ any inducement or subterfuge to gain an interview. No fee should be paid or offered for the granting of an interview. Donations to charities in return for healthcare sales representatives gaining interviews are prohibited. Offering or making donations in lieu of hospitality are unacceptable. In an interview, or when seeking an appointment for one, healthcare sales representatives must at the outset take reasonable steps to ensure that they do not mislead as to their identity or the company that they represent.
- Consideration for healthcare professionals and others: Healthcare sales representatives must ensure that the frequency, timing and duration of calls on HCPs, pharmacies, hospitals, other healthcare facilities, medical schemes or funders and the like, together with the manner in which they are made, do not cause inconvenience. The wishes of individuals on whom healthcare sales representatives wish to call, and the arrangements in force at any particular establishment, must be observed.
- Healthcare sales representatives in an operating room or clinical environment: Healthcare sales representative must be appropriately trained on operating room/clinical environment protocol(s) and:
 1. May only enter an operating room/clinical environment upon permission from appropriate members of the medical staff of the facility.
 2. Must wear appropriate attire as provided by/or approved by the facility.
 3. May only advise on technical aspects of company products consistent with the approved package insert.
 4. May not give clinical diagnostic advice, surgical advice or recommend treatment, even as the result of a direct request from the surgeon, operating room staff, or any other healthcare professional.

5. May not use and/or apply company product, deliver patient or medical care directly to a patient even with appropriate certification/licenses

2) Interactions with HCPs

- Hospitality/venues of meetings and events: Companies, organisations or individuals are permitted to organise or sponsor meetings and events including continuing professional development (CPD). The following should be adhered to:
 - The merit and focus of the meeting should be clearly scientific and/or educational.
 - The venue and hospitality should be secondary to the meeting both in time allocation and focus.
 - The venue should be appropriate and conducive to the scientific or educational objectives and the purpose of the event or meeting.
 - Hospitality, meals and entertainment should be modest. As a general rule, hospitality must not exceed what the healthcare professionals would normally be prepared to pay for themselves.
 - Invitations should not be extended to spouses or other guests except if they are healthcare professionals or administrative staff i.e. any costs incurred by spouses or other guests cannot be reimbursed or paid for by the company.
 - Inappropriate financial benefit or material benefits including excessive hospitality cannot be offered and/or extended to healthcare professionals.
 - For speakers, payment of reasonable honoraria and reimbursement of out of pocket expenses, including travel are permissible provided it is in terms of a written contract and on submission of original invoices.
 - Sponsorship of healthcare professionals to attend congresses and the like, should not be used to influence them to promote specific health products.
 - For local CPD events and product launches which are held in major cities, reasonable travel arrangements or travel reimbursement can be made to ensure that the

HCPs that do not reside/practice in major cities are able to access the applicable information.

- The criteria for selection of attendees/invitees must be transparent.
- For medical or scientific congresses, conferences or seminars held in SA, internationally or international meetings held overseas and held in SA:
 - Meetings organised by companies, other organisations or individuals at venues outside SA, that are educational and scientific in nature and involve SA HCPs are acceptable. It is inappropriate to host HCPs at venues that would be considered holiday destinations and which are distant from their normal place of practice, unless it is a bona fide educational meeting, conference or congress, endorsed by a professional healthcare association.
 - The rationale for any meeting, or sponsorship to attend a meeting, is to be transparent, valid and cogent.
 - Consideration must be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, hospitality provided and the like.
 - As with any meeting, it should be the programme that attracts delegates and not the associated hospitality or venue and all entertainment and events have to be subordinate in time and nature to the sponsored meeting, congress, conference or seminar.
 - Payment of registration fees, travel and accommodation must be made to the professional associations/organisers and not directly to the HCP or appropriate administrative staff, unless proof is received that the amounts spent are in the name of the sponsored person and which corresponds to each and every line item as per the agreed sponsorship. No payment may be made to the professional/staff for time spent at the event.
 - Sponsored speakers may receive reasonable honoraria.

- Sponsorship of congress organised events, other than recreational and sporting events, is permitted. However sponsorship of any stand alone social or entertainment event is not permitted.
- It is inappropriate to host or sponsor meals or receptions for large groups of HCPs that are entirely unconnected to any congress, business premises or educational event.
- Light entertainment in the form of background music at events connected to a bone fide function for the exchange of information is acceptable.
- Business class travel is permitted for only incoming and outgoing faculty members, namely HCPs that are presenting scientific papers at the congress, educational events or local CPD accredited meetings/events on the day of arrival.

3) Transparency

- When meetings are sponsored by companies, other organisations or by individuals, the fact must be disclosed in the papers relating to the meetings and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it at the outset.
- Stand-alone entertainment, leisure, social or cultural events with healthcare professionals
 - Meetings organised for patients, general public, individual or groups of doctors, other HCPs and/or for administrative staff that are wholly or mainly of an entertainment, leisure, social or sporting nature is not permitted.
 - No stand-alone entertainment or other leisure, social or sporting activities may be planned, arranged or funded by companies as these are unrelated to the promotion of scientific or educational objectives.

4) Consultancy services

Consulting services should be legitimate, have a business need and be governed by a written service level agreement. The contract for consulting or other services can include but is not limited to:

- Speakers for conferences and congresses;

- Presentation and demonstrations at company sponsored product training;
- Advisory boards;
- Training services;
- Development of educational material/software or programmes;
- Development and/or management of patient compliance software/programs.

5) Payments to healthcare professionals for any other services

- Payments may not be made to doctors or groups of HCPs, either directly or indirectly, for rental for rooms or other services.
- HCPs involved in *bona-fide* and if relevant, peer reviewed research, are not subject to the above.

Inducements, gifts and promotional items, competitions

1) Inducements

There should be no personal enrichment of HCPs or other healthcare providers. No gift, benefit in kind, rebate, discount, kick-back or any other pecuniary advantage shall be offered or given to members of the health professions, administrative staff, government officials, or the general public as an inducement to prescribe, lease, loan, supply, stock, dispense, administer or buy any healthcare product. No donation should unjustifiably enrich healthcare professionals performing a health related service.

2) Gifts and promotional items

Occasional gifts and promotional items to healthcare professionals, appropriate administrative staff, sales and other staff are acceptable provided that they are:

- Inexpensive and of minimal intrinsic value i.e. within a cost limit set from time to time per annum. The current value is R300 inclusive of Vat.
- Not for personal use, for example no entertainment CDs/DVDs, electronic items for entertainment, tickets to attend sporting events or other forms of entertainment.
- Educational and/or of scientific value, benefit the patient and/or be relevant to the practice.
- No cash or cash equivalents is allowed.
- With regard to scientific medical reference books, journals, periodicals and anatomical models in-

tended for teaching or patient benefit: For individual practising HCP or practises, it should not exceed R2 500 inclusive of VAT/year. For training or academic institutions, it should not exceed R10 000 inclusive of VAT/year.

3) Cultural courtesy gifts

The medical device and *in vitro* diagnostic (IVD) industry may not give gifts pertaining to cultural, religious or national events.

4) Promotional items: intended for use by patients

Some items distributed as promotional aids are intended for use by patients and these are acceptable provided that they are inexpensive (not more than R300 including VAT) and relevant to the practice. No gift or promotional item for use by patients must be given for the purpose of encouraging patients to request a particular health product.

5) Competitions

The use of competitions, quizzes and suchlike for the purposes of sales promotion is an acceptable form of promotion. A competition is acceptable if its subject matter is clearly related to the practice of medicine and pharmacy. Entrance into the competition should not be linked to the sale, recommendation or prescription of the product in any manner or form. The maximum per prize in a promotional competition is R2 000, including VAT/event or promotional activity. If the prize is congress sponsorship, it will cover *bona fide* conference fees, accommodation and travel for the winner only.

6) Donations and grants to charities

Financial donations or other appropriate donations to registered charities or other institutions may be made if properly recorded and approved by the responsible person(s) in each company or organisation. Donations, grants and benefits in kind to institutions, organisations or associations are only allowed provided:

- They are made for the purpose of supporting healthcare or research;
- They are documented and kept on record by the donor/grantor; and
- They do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. Donations must not be paid directly to healthcare professionals.
- No donations may be made to hospitals or clinics as an incentive to prescribe any health product.

7) Samples

The purpose of a sample is to permit a HCP to evaluate the clinical efficacy of a product. Samples may only be provided to individual HCPs for their professional evaluation in the course of their clinical practice. Samples may not be provided to hospitals, hospital groups or other healthcare providers. The legislation^[5] does not permit sampling of combination products, namely products that include a registerable component.

8) Product evaluations

The situation frequently arises in SA that medical device companies wish to have local healthcare practitioners evaluate a new device; this is either prior to a launch of the product nationally, or in combination with a launch, where supply companies are seeking to obtain the views of key decision makers regarding the suitability of their device for the South African market.

9) Meals

Modest meals may be provided as an occasional business courtesy consistent with the following limitations.

- The meal should be incidental to the bona fide presentation of scientific, educational, or business information and provided in a manner conducive to the presentation of such information. The meal should not be part of an entertainment or recreational event.
- Meals may occur at the HCPs place of business. However, in some cases the place of business may be a patient care setting that is not available for, or conducive to, such scientific, educational, or business discussions. In other cases, it may be impractical or inappropriate to provide meals at the HCPs place of business, for example, (i) where the medical technology cannot easily be transported to the HCPs location, (ii) when it is necessary to discuss confidential product development or improvement information, or (iii) where a private space cannot be obtained on-site.
- Meals can only be provided to HCPs who actually attend the meeting. Meals for guests of HCPs or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting is not allowed.

10) Terms of trade

Schemes that enable healthcare professionals to obtain personal benefits in relation to the purchase of health products are unacceptable even if they are presented as alternatives to financial discounts.

11) Transparent Invoicing^[4]

- Companies should support the provision of accurate, transparent and responsible billing information to reimbursement authorities and other payors.
- Specifically, no company may offer a rebate or other off invoice discount to a HCP in relation to the acquisition of goods and services.

12) Acquisition of Information^[4]

Companies may purchase information/data subject to the following:

- Information/data fees must be related to the rendering of a bona fide service, commensurate with the value of the services rendered and which are not linked to sales, volumes, targets or similar criteria.
- Unacceptable data fees mean: data fees which are used to encourage or increase the purchase, loan or use of a medical device and which data is of no or limited value to the buyer and which is bought solely, or mostly in order to reward or secure a particular purchase or utilisation behaviour, and which is not reduced to writing and for which the fees are not commensurate with the nature, potential use or type of data, and which is linked to sales value and/or sales volume and/or preferential usage or recommendation of any medical device.

SAMED reserves the right to call for details of contracts entered into in this regard. These products may have FDA or CE approval and are new to the South African market, but approved for use in other international markets.

The implementation of product evaluations in SA should be conducted in accordance with the following guidelines:

- No payment may be made to the healthcare practitioner involved in the evaluation. If any payments are made, the evaluation must be done in full compliance with the rules of clinical trials/product registries.
- The products may be donated free of charge for the evaluation.

Where an evaluation is conducted and monies exchanged:

- There must be a written contract, and
- Tangible written evaluation results must be provided.

All evaluations must have a finite time period or alternatively a finite number of procedures to be performed.

Enforcement

The Code is binding on all SAMED companies and is a condition for new and ongoing membership. The Code will be continuously reviewed, borrowing from best practice both locally and globally. In fact much of what appears in SAMEDs Code has been adopted from the Eucomed^[2] and Advamed^[3] codes of business practice.

The Code will be enforced through the efforts of a formally constituted SAMED Ethics Committee governed by documented and legally compliant processes. In addition, the latest amendments to the Medicines and Related Substances Act,^[5] will elevate the status of the Code to that of regulations, when published by the Minister of Health in terms of section 18C of the Act.

Conclusion

The medical device industry worldwide is increasingly recognising that adherence to ethical standards and compliance with applicable laws are critical to the medical devices industry's ability to continue its collaboration with HCPs. Companies must encourage ethical business practices and socially responsible industry conduct related to their interactions with HCPs. Companies must continue to respect the obligation of HCPs to make independent decisions regarding treatment.

SAMED^[9] in particular is committed to the establishment of a healthcare system that is ethical, people centred, equitable, coherent and efficient and in particular to the contribution that high quality, cost-effective healthcare technology can make toward achieving those goals.

Thus, in pursuing this mission, the Code recognises, respects and encourages adherence to ethical standards and compliance with both the spirit and letter of applicable laws and guidelines in all business endeavours.

SAMED recognises that all South Africans have a right of access to healthcare, and that right should be progressively realised through co-operation and shared responsibility between the SA medical device industry and the SA health care profession.

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