The South African Medical Technology Industry Association (SAMED)

Submission

on the

Draft General Regulations Relating to Bonusing

Submitted to:
National Department of Health
Director: Pharmaceutical Economic Evaluations Directorate

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Contact Information:
Chief Executive Officer
Tanya Vogt
Tel: +27 (0)11 704 2440
Mobile: +27 83 601 0343
Email: tanya@samed.org.za

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1. Introduction

SAMED – The South African Medical Technology Industry Association – represents the interests of our members i.e. medical device, medical equipment and in vitro diagnostic (IVD) companies in South Africa.

A key objective of SAMED is to provide our members with a collective, objective and credible platform to engage with all stakeholders on matters of significant importance to the industry.

SAMED has grown considerably over the last few years and currently represents 164 member companies - who are involved in the manufacture, import, sale, marketing, wholesaling and distribution of medical technologies in South Africa. Although SAMED has urged its members to make individual submissions on S18A(1) draft regulations, we have also engaged various sectors of our membership and arrived at the following submission with a view to submit commentary on business models / practices common to industry. SAMED obtained the information under the auspices of an independent, legal third party to provide aggregated anonymized information.

SAMED supports the overarching objective and intent of the draft regulations i.e. to prevent perverse activities, ensure affordable medical devices and IVDs and a transparent pricing system of medical devices and IVDs.

2. Compliance and monitoring

SAMED requests that prior to the finalization of these regulations, a regulatory body or department, be put in place to give effect to the regulations, where contraventions can be monitored, reported etc. Compliance becomes anti-competitive if only a handful of suppliers comply. The cost of implementing compliance measures and/or changing business models can be costly and as such SAMED requests that sufficient resources and attention be paid to ensuring that all companies adhere to the regulations.

3. Alignment with other legislation and reimbursement practices

SAMED proposes that these regulations be aligned to all legislation / regulations that allow for donations, grants and sampling and that currently allow for any of the cited prohibited activities.

Such legislation might include: the Public Finance Management Act; the Preferential Procurement Policy Framework Act and associated regulations; the Health Professions Act and associated ethical booklets; the Code of Conduct: Public Service Regulations; Guidelines with regard to Clinical Trials; the Medical Schemes Act which allows for Designated Service Providers where preferential pricing and negotiated discounts occur etc. Clarity is sought as to whether such prohibition includes similar contributions to the State. SAMED also recommends that in the final drafting of these regulations, cognizance be given to the outcomes of the health market inquiry

Medical devices and IVDs are often input costs that are reimbursed as a procedure fee that includes professional HCP fees and hospital/institutional costs. SAMED supports efforts that increase transparency and ensures that savings and discounts are passed onto the patient. Although the Fee for Service model is the norm in SA alternative models e.g. global procedure fees and risk sharing are becoming more common. In many instances these drive down overall healthcare costs.

The downstream impact on prohibiting certain practices as stipulated in the regulations need to be properly understood as it could have a negative impact on patient management; access to care and overall healthcare costs.

In instances where the provisions of Section 18A overlaps with Section 18B and certain practices are permitted under Section 18B, e.g. placements under 18A and free supply under 18B then such practice should be allowed under Section 18A and vice versa.

4. SAMED Support of Regulations

SAMED, in principle supports the prohibition of the following activities, where the intent is perverse:

1.1. Regulation 5(a) a discount in respect of rebates only and these should be differentiated from discounts. Rebates rewards the user after utilization at a certain rate, volume or value and therefore influences behavior of users in anticipation of a reward. And this results in perversity and non-transparent transactions. Rebates are also not defined and SAMED proposes that a definition be provided.
1.2. Regulation 5(b) payment for marketing, promotion, and advertising*
1.3. Regulation 5(c) fees for shelf space.*
1.4. Regulation 5(d) data fees and registry fees etc.
1.5. Regulation 5(e) loyalty fees or similar fees.
1.6. Regulation 5(f) director's fees etc.
1.7. Regulation 5(k) unjustified credit payments which have the effect of an inducement.
1.8. Regulation 5(h) payment or contribution by a supplier towards any recurring expenditure.

*SAMED would submit however that in certain sub-sectors of healthcare e.g. borderline medical devices/self-care devices where the patient can access the device directly, without the need for an HCP such practices may be acceptable as in an FMCG type trading environment.

SAMED agrees that it would be deemed to be perverse or unacceptable to carry the business expenses of another business, however, in this case only "recurrent expenditure" is prohibited.

SAMED requests that the Director General review regulation 5(h) and provide clarity as to why only 'recurrent expenditure'.

Section 18A(2) provides that the Minister may provide acceptable and prohibited acts. Through these draft regulations, the minister as only provided prohibited acts. SAMED foresees that industry may interpret this to mean that anything that is not prohibited under the draft regulations is automatically acceptable by virtue of such exclusion. In order to avoid such a situation, SAMED proposes that the Minster prescribes the acceptable acts.

5. Section 18C and Marketing Codes

With regard to regulation 5(g) entertainment costs, meals etc, SAMED is very supportive and proposes that the Minister bring into effect S18C of the Health Act which provides that the Minister, in consultation with the pharmaceutical industry and other stakeholders, may create regulations relating to marketing of medicines, medical devices and IVD's.

These regulations shall provide for an enforceable Code of Practice for relevant industries thereby ensuring an equal playing field for all participants in the sector.

SAMED hereby requests that the Minister endorse the Medical Device Code of Ethical Business and Marketing practice and make it a legal requirement for all medical device and IVD companies to abide by the publication of regulations under section 18C to this regard. While the Code prohibits medical device and IVD companies from the direct sponsorship of healthcare professionals to attend local and international third party organized educational events, continued education for Healthcare Practitioners (HCPs) on new procedures, techniques and products remains important for the elevation of healthcare within the country as well as the improvement in patient outcomes. Therefore, sponsorship to third party procedure events and company events is still permitted provided the event is intended to support the exchange of scientific and medical information.

Grants can only be provided to third parties e.g. professional associations but never to individuals. Grants will also require a written contract. Companies may define the category of HCPs eligible for financial support but not choose individual HCPs.

The Code can be accessed at http://www.samed.org.za/Codes-of-Practice.aspx

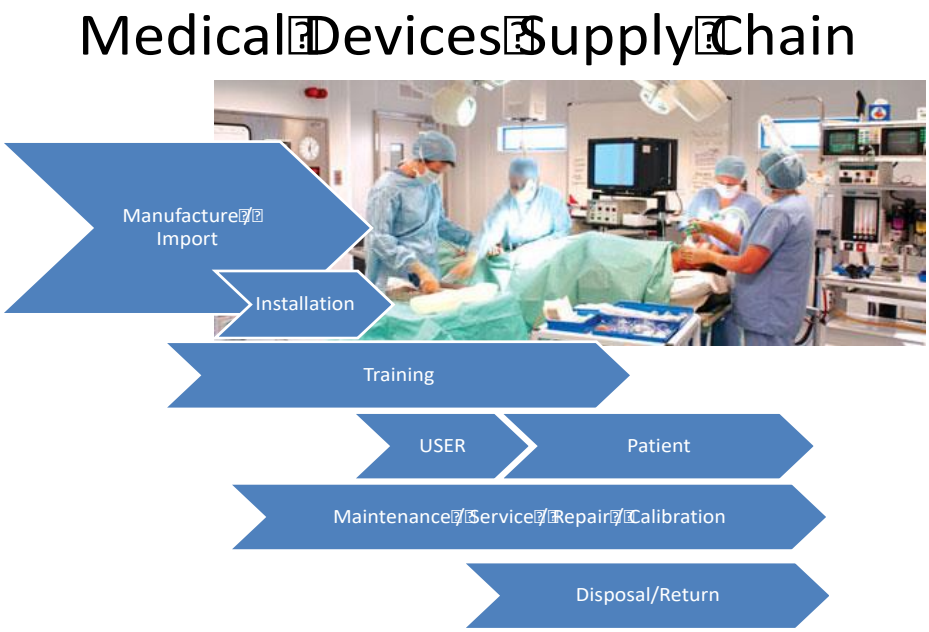
6. SAMED request for review of regulations

SAMED respectfully requests that the Director General consider allowing the following activities, that the regulations seek to prohibit, to continue in the market place. A rationale or motivation for such allowance is provided and where relevant proposals are offered as to how to prevent perversities:

6.1 Regulation 5(a) Volume or ‘bulk purchase’ discounts

SAMED is concerned that the phrase: “or for any other reason” as used in the draft regulations (under the definition of “discount”) is a vague provision and requests that the Director General consider either removing the clause or replacing it with a specific activity. Such liberal use of terms may result in misinterpretations, confusion, commercial uncertainty and legal challenges.

There are different categories, variants, models and types of Medical Devices, which follow different supply chain routes and hence various volume or ‘bulk purchase’ discounts apply accordingly. See figure 1:



This figure represents the supply chain applicable to most device companies. Prior to buying a medical device, a Healthcare Professional (HCP) and/ or Healthcare Organisation e.g. hospital and/or patients receive a demonstration on how the device works. Although not depicted in this figure. HCP will not purchase the device until there has been a demonstration and they have been able to test the device. After the installation of the device, training is provided on the use of the device. If a purchaser buys one device the cost of the training is set off against the sale of one device, while, if there are volume purchases, the cost of the training is set off against the purchase price of multiple devices, making it less expensive for the supplier to provide the training and enabling a discount.

For maintenance / repair purposes, the device may have to be removed from the institution and in order to continue operations, the arrangement in most instances is to loan the institution another device.

In the ordinary course of events, volume discounts are generally seen as pro-competitive unless they are predatory or discriminatory and exclusionary (in the context of dominance), and even then, such a practice must result in the substantial foreclosure of market players, in which case and in this instance, it should be prohibited. Volume discounts must also be differentiated from rebates. Rebates reward the user after the fact and influence behavior of the user due to the expectation of a reward.

Volume discounts may help reduce the cost of health care because medical schemes may secure better hospital care rates for their customers (patients) than an uninsured customer. For the uninsured customer, access to the equipment may be cheaper than it would otherwise have been. This is particularly important as the healthcare sector tries to provide greater cost transparency to a patient so that they may make an informed decision when deciding to follow recommended treatments or not. A lower price that is passed onto the patient would be an important determinant.

As a result, tender prices are often more competitive as they are accompanied by high volumes and therefore justify lower prices. This alleviates the financial burden on the state and benefits the patient.

Based on the above SAMED urges that volume and bulk discounts not be prohibited as they do not constitute a perversity, or something that is not in the patient's best interest. For example, an agreement with a low-income medical scheme to ensure member access to health services should be permitted, provided that it does not set a target that substantially forecloses that market for others, or lead to the inappropriate use of a device

Volume discounts are often connected to economies of scale and other costs e.g. the logistics cost to service a customer who orders less volumes is higher (per unit) than the costs of servicing a customer who orders more.

Higher volumes allow for better price negotiations. Large groups e.g. the NHLS use buying power to drive prices down; promote standardization on platforms; necessitating less training, less stock holding of various types of spares resulting in a much lower cost of ownership. A lower price that is passed onto the patient would again be an important determinant.

There is no clear definition on what a "published selling price" entails, especially for medical devices and IVDs. Medical device prices are often negotiated on tender or formulary with discounts as common practice. Prohibiting a discount on this price may well drive up the cost of healthcare. This model seems to assert price regulation on MD/IVD even in the absence of SEP.

Proposal on how to prevent perversity

All discounts must be indicated on the invoice. The Medical Device Code of Ethical Marketing and Business Practice advocates for this. See: Medical Device Code

A written contract must be in place which can be called upon in the case of a complaint to the regulator. Suppliers and customers must be able, if called upon, to show that discounts have been passed on to / benefit the patient.

6.2 Other forms of discounts / bonus deals

The word bonus is not defined in the definition clause of the regulations. SAMED proposes that a definition be supplied, along the following: "*provision of a free good or goods with the medicine or device to a patient whether such good or goods is the same or similar to the said medicine or device".*

Rationale for allowing this to continue

Discounts that directly benefit a patient should be allowed to continue e.g. cardiovascular and orthopaedic implants, where the funder reimbursement amount is lower than the list price or where the patient's benefit package does not cover the full cost of the device, companies should be allowed to discount the price to prevent out of pocket payments by patients. This in turn ensures that Healthcare Professionals (HCP's) are able to choose medical devices that are clinically indicated for their patient even if the price is above that of what the patient can afford.

Some discounts are applied to an upgrade or new technology in order to ensure that the health professional can access such technology and therefore benefit the patient.

6.3 Settlement discounts

Rationale for allowing this to continue

Settlement discounts are a standard business practice and are used to encourage timeous payment in order to promote positive cash flow (especially for smaller companies) and prevent incurring finance costs due to late/non-payment i.e. interest which if charged might be passed on to the patient.

Such business practice should be retained provided it is transparent and applied equally to all parties. Provincial Departments of Health are very poor payers, for example, and it is commonplace for companies to have monies owed to them in excess of 180 or more days.

Cash payment for achieving sales targets would constitute market foreclosure under the Competition Act in certain circumstances, and/or be unethical if patient interests are not catered for. This practice should be prohibited.

Proposal on how to prevent perversity

SAMED proposes that settlement discounts not be prohibited and further proposes the following in order to prevent perversity:

Settlement discounts must be indicated on the invoice and must be of fair market value. A written contract must be in place which can be called upon in the case of a complaint to the regulator. The supplier must have a policy for the application of the discounts in order to ensure fair application thereof, which means no product offering is specific to only one customer.

6.4 Regulation 5(i) free services rendered by suppliers or their agents to customers which has the effect of (h)

The following are free services provided by the industry:

- Product support fee or other payment to Private Nursing Practitioners on the use/application of a company's medical device or for training provided on the medical device
- Representative offering assistance in theatre in keeping with the SAMED endorsed CRICE principles
- Market access support to doctors and patient
- Compliance support and patient education programmes
- Payment by medical device companies in relation to medical device registries
- Maintenance and repair services, software upgrades and updates
- Compliance and adherence services by suppliers to ensure that treatment is undertaken as indicated or that devices are utilised correctly.
- Educational services and disease awareness education to the patient or patients.
- Public campaigns that often include screening for diseases where these services and products are freely provided.
- Replacement of product/device during a recall.

SAMED seeks clarity as to whether the prohibition of free services encompasses the above practices and how they would be impacted. We would strongly urge that these practices be allowed to continue on the basis of patient empowerment and interest. Some of the above practices are required by consumer legislation and regulations. Patients require training on the correct and safe use of the product.

The highly complex and technical nature of medical devices require highly specialized technical support. This technical expertise may vary significantly from device company to device company and as such would not make sense to expect this specialized experience to be located 'in house' at hospitals. Suppliers consider it their responsibility to provide this support in the interests of patient safety.

6.5 Regulation 5(j) Incentive scheme: the placement or the provision of any equipment.

Rationale for allowing this to continue

SAMED requests that a differentiation be made between rental placement and placement at no costs and out-right purchase. Placements are an accepted practice internationally. They are negotiated, often via a tender process and the customer has a choice.

The benefits of allowing placement of equipment include:

- Improved access to devices/technologies that some institutions may otherwise not be able to afford. This is especially applicable in the public health sector with limits being placed on the departments.
- Access to the latest technology e.g. upgrades to device/medical technology where the latest model is placed without additional capital expenditure. The patient benefits through access and low cost.
- Newly diagnosed patients will have access and choice
- Free upgrades to the latest technology (upgrades) without costs to the institution- thereby improving access for the patient.

For the aforementioned reasons, SAMED urges that the practice of placements is not prohibited.

Proposal on how to prevent perversity

SAMED proposes the following addition (reference: the Medical Device Code of Ethical Marketing and Business Practice):

Loan or placed equipment:

The sale, loan/rental or placement of equipment with a customer, where the contract between the member and the customer includes the purchase of consumables / disposables associated with the equipment, are subject to the following provisions:

- HCPSA's Guidelines for Good Practice in the Healthcare Professions – Booklet 11, item 3.6 Technological Equipment:
  - HCPs shall only own and use technological equipment if it forms an integral part of their scope of the profession and practice and on condition that the HCP concerned has received appropriate training in using and managing such equipment.
  - HCPs shall not over-use equipment for procedures, tests and other applications that are not indicated, scientific or evidence based. This constitutes over-servicing and is prohibited.
  - HCPs shall not use technological equipment, healthcare products or devices for profiteering and must refrain from charging patients fees for the use of such products or devices that are not market related.
- The consumables are used to cross-merchandise the capital equipment in a manner which is defensible and fair.
- The consumables relate to the specific piece of capital equipment being financed by means of the purchase of the consumables and is defensible in terms of the provisions of the National Credit Act.

- The placement of equipment agreement should be in writing and, in cases of valid complaints, made available for review.
- In the case of equipment licensed with the Radiation Board, such equipment may only be loaned or placed as stipulated in the product license as issued by the Radiation Board.
- Interchangeable consumables must be considered as an advantage to improve competition. However the fact that certain equipment may only be used with certain consumables should not be considered to be undesireable, but rather directed at ensuring the integrity of the equipment, to maintain the warranty (i.e. mitigating against higher maintenance costs) and most importantly, patient safety.

6.6 Regulation 5(j) consignment stock

Rationale for allowing this to continue

Although the consignment model is expensive from a supplier/distributor perspective since they have to carry large volumes of stock, the Consignment model allows for a better treatment flow and accessibility to products, where the device or product required by the patient may not be ascertained beforehand: e.g. if a patient is on the operating table and a specific device is needed, the stock is immediately at hand; as opposed to having to take the patient off the table, ordering the device, bringing the patient back onto the table and then completing the treatment regime. In emergency cases, this is critical. In both emergency and non-emergency cases, costs, such as theatre/cathlab/ward costs, are significantly reduced by having this type of access. Other factors to consider:

- Emergency cases such as injuries, fracture etc. don't allow items to be sourced before hand
- Exact sizes often only determined at time of procedure
- The HCP has freedom of choice on the best device for the specific patient
- It provides access to patients and best choice treatment
- It also improves competition, allowing smaller player to also place their stock in the institution

Proposal on how to prevent perversity

- Customers must have a choice e.g. comparison through tender
- All approved suppliers must be allowed to place stock
- There must be an agreement in place and the supplier must be responsible for expiry, quality access and traceability.
- The hospital must monitor the flow in order to prevent being charged for stock without record of use.

6.7 Regulation 5(j) Loan sets

SAMED proposes that this practice not be prohibited based on the following rationale:

SAMED requests that a definition for loan sets be provided, for example, a number of definitions prevail in the market place such as:

- Loaned equipment that replaces a damaged device allows for continuity in provision of care at no additional cost to the patient.

- Loan sets that are used as tools in surgical implants/procedures are rotated between centers/hospitals by suppliers. This is done after the choice of device has been made and reduces overall healthcare costs as each hospital doesn't then have to own each set for use only on 1 or 2 days. Loan sets as placements (see SAMED's proposal regarding placements)

Loan sets/equipment are typically provided in the following circumstances:

1. For use in a particular procedure together with consumables (e.g. spine loaner sets that are loaned together with the spinal screws for implantation)
2. Where a healthcare facility is unable to afford capital equipment and/or would like to determine whether there is sufficient need for a particular type of procedure to justify the purchase of such capital equipment
3. Capital equipment loaned for training and educational activities
4. Where required pursuant to tenders (in public sector often required to place capital equipment to be used with consumables under tender.

Proposal on how to prevent perversity

- Contract agreement to be in place
- Adherence to SANS standard 1541:2:2014

7. Section 18B of the Medicines and Related Substances Act

Although the draft regulations relating to bonusing does not mention 18B, SAMED proposes that in reviewing the draft regulations, consideration be given to the publication of regulations relating to sampling, demonstration and evaluation of medical devices and IVDs, as opposed to samples intended as "an incentive scheme". In this regard donations to state and for clinical trials and evaluation should be permitted.

Most practitioners and institutions will not buy a medical device prior to that product having been evaluated/trialed or demonstrated. However, in instances where the medical device does not have a Nappi code, some institutions tend to abuse the system by using it to save costs by trialing a device/product for unreasonable periods of time. This can be prevented by regulating that there should be a trial for a reasonable period of time required for that specific purpose. See also Appendix 1.

Failure to provide the product for validation or demonstration may disqualify the supplier from tendering in both private and public.

In some markets, e.g. audiology, the patient is allowed to trial a medical device prescribed by the healthcare professional for a limited time to ensure compatibility and functionality. This also removes barriers such as fear and uncertainty, reduces the acclimatization period etc. Sampling is very costly to suppliers and as a result it is limited as much as possible.

Bona fide donations through non-profit organisations and philanthropic acts, such as donating short-dated stock to needy patients should be allowed.

SAMED proposes that Chapter 6 (Demonstration products and samples) from the Medical Device Code of Ethical Marketing and Business Practice be considered for input into regulations. (See appendix 1)

8. Concluding remarks

SAMED reaffirms its support of the overarching objective and intent of the draft regulations i.e. to prevent perverse activities, ensure affordable medical devices and IVDs and transparent pricing within the healthcare system.

SAMED wishes to emphasize the differences between medicines and medical devices & IVDs and is appreciative of the current exemption in place for the latter so that there can be ongoing engagement in this regard.

SAMED cautions that there may be inadvertent cost implications to some of the blanket prohibitions suggested in the regulations, which defeat the purpose of the regulations and hopes that the examples provided highlight this. The practices have the effect of reducing overall cost. That this is passed onto the patient would be the important determinant.

SAMED would like to request further, direct engagement between government and all relevant stakeholders to ensure that there is effective prevention of perverse business practices without negative impact on patient outcomes.

We look forward to a fruitful and constructive engagement on this important piece of proposed legislation.

9. Appendix 1: Demonstration products and samples

(from the Medical Device Code of Ethical Marketing and Business Practice)

Demonstration products and samples

This chapter is limited to the provision of demonstration products and/or samples and related services at no charge.

1. Definitions

Demonstration products (demos): means either single-use or multiple-use products provided free of charge by or on behalf of a member company to Healthcare Organisations (HCOs) or HCPs, who are equipped and qualified to use them. Demos are supplied solely for the purpose of demonstrating safe and effective use and appropriate functionality of a product and are not intended for clinical use. Demos do not include the following:

- Samples.
- Evaluation products.
- Products provided at no charge as part of a charitable donation or as part of a research or educational grant.
- Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

Evaluation products: means either single-use or multiple-use products and/or equipment provided free of charge to a healthcare institution by or on behalf of a member company for purposes of obtaining defined, evaluative user feedback over a defined period of use when used within the scope of their intended purpose. Evaluation products do not include the following:

- Demos.
- Samples.
- Products provided at no charge as part of a charitable donation or as part of a research or educational grant.
- Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

Samples: means single-use or multiple-use products provided free of charge by or on behalf of a member company to HCOs or HCPs who are equipped and qualified to use them in order to enable HCPs to familiarise themselves with the products in clinical use. Samples do not include the following:

- Demos.
- Evaluation products.
- Products provided at no charge as part of a charitable donation or as part of a research or educational grant.

Products provided at no additional charge as part of the overall purchase price in a commercial supply arrangement, e.g. as part of an agreed discount arrangement, or as substitute products provided pursuant to a warranty agreement.

2. General principles

Companies may provide their own products as demonstration products and/or samples (see the definitions above) at no charge in order to enable HCPs and/or HCOs (as applicable) to evaluate and/or familiarise themselves with the safe, effective and appropriate use and functionality of the product and/or related service and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

Demonstration products and/or samples may be either single- or multiple-use products. Companies may also provide products from another company in conjunction with the member company's own demonstration products and/or samples on an exceptional basis if those other company's products are required in order to properly and effectively demonstrate, evaluate or use the member company's products, e.g. computer hardware and software produced by a company other than the member company.

Provision of demonstration products and/or samples must not improperly reward, induce and/or encourage HCPs and/or HCOs to purchase, lease, recommend, prescribe, use, supply or procure companies' products or services. Any offer and/or supply of such products shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct.

Companies 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. Companies 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.

3. Demonstration products (demos)

Companies may provide examples of their products to HCPs and/or HCOs in the form of mock-ups (such as unsterilised single use products) that are used for HCPs and patient awareness, education and training. For example, a HCP may use a demonstration product to show a patient the type of technology which will be implanted in the patient or may use the demo to train other HCPs in the use of the product.

Demonstration products are not intended for clinical use in any patient care nor are they intended for on-sale or other transfer. Companies 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 no later than the time of the supply. It is recommended that the disclosure to HCPs and HCOs shall be in writing.

4. Samples

Companies 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 a 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.

Companies shall in all cases ensure that they retain title to multiple-use samples and that they have a process in place for promptly removing such multiple-use samples from the HCP's location at the conclusion of the familiarisation period.