

## **SAMED compliance guidance document on emergency support during Covid-19 crisis**

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

#### **Objective & introduction**

In the current COVID-19 crisis manufacturers and distributors of medical technologies (SAMED companies) need fast decision-making to support Healthcare Professionals (HCPs), Healthcare Organisations (HCO), healthcare systems, the private and public health sector on their efforts to combat the pandemic.

This guidance document aims at supporting SAMED Member companies' legal and/or compliance teams when considering emergency processes to fast-track requests related to the COVID-19 crisis to the benefit to society while attempting to limit the inherent compliance risks.

The implementation of the Disaster Management Act does not normally imply the automatic derogation of contractual or legal obligations, therefore, requests from public bodies or agencies that would in normal times contravene laws and regulations may still contravene them, even if the request happens while the Disaster Management Act is in effect.

This Guidance document is not intended to supplant or supersede any national laws or regulations or professional codes, including company codes and companies' internal policies. The current situation is very fluid, and applicable laws change in a matter of hours through ordinances, decrees and other emergency legislative mechanisms.

It is therefore crucial for all parties involved to seek support from their legal and compliance teams along with local legal counsel when considering providing certain emergency support or requests as described below. In addition, any guidance included in this document must be understood as relevant only provided local laws and regulations allow for such arrangements.

### **Types of emergency support/requests**

The last weeks have brought to light examples of products and services supply which is needed urgently in COVID-19 affected countries, such as, but not limited to:

- Free-of-charge temporary loans of medical equipment.
- Free-of-charge temporary software licenses/cloud service subscriptions.
- Donations of single/multiple use products
- Loan of staff/remote workforce (e.g. trained HCPs, logistics specialists).
- Special payment arrangements.
- Donations of financial support on a humanitarian basis to support HCO's employment of temporary additional staff resources as needed, and purchase of additional products or services required through the COVID-19 crisis.

See, for example, regarding some aspects of Chapter 4 of the Code: Charitable Donations.

For avoidance of doubt, any emergency support, even if based upon a legitimate purpose and in *bona fide*, comes with certain risks. Therefore, each Member Company is advised to consider legal and compliance considerations prior offering their support such as, but not limited to, competition law, anti-corruption/anti-bribery laws, transparency/disclosure requirements, labour laws and tax/finance laws, as well as relevant insurance coverage and liability regimes.

For more information on placement of equipment, please refer to Chapter 7 of the Code: Loan or placed equipment.

### **Guidance**

Given the current COVID-19 crisis, SAMED acknowledges that some parts of this guidance may contradict the Code and therefore, this guidance must be understood as superseding

those provisions when dealing with requests related to COVID-19, for the duration of the crisis and until the current situation passes.

In this sense, SAMED companies must clearly document the link between the support provided and the COVID-19 crisis, and when this link cannot be clearly established, or in an ongoing support, this link ceases to exist, the default rules of the Code must be applied.

## **Principles**

Exceptional circumstances may, in principle, not serve as an excuse for non-compliance to any laws and regulations. As such, when dealing with any request related to COVID-19, the principles of the Code should always be applied, but in some cases the current situation may require that principles be applied in a different way than in normal times. Therefore, responses to such requests must:

- Be free from any intent to improperly induce purchase of products or services.
- Be fully documented to allow for detailed transparency.
- Always consider the perception and the image of the industry.

When dealing with grants and donations, decisions must be made independent of the sales process and in an unbiased manner.

Under supervision of the company's Legal/Compliance department, an internal ad-hoc fast-track process can be considered in order to ensure appropriate documentation and to track the general approval of the emergency support requests related to COVID-19 as listed below, and others.

All kinds of support should be properly documented. Where urgency may require acting before an internal process can be properly completed in advance, all steps and approvals should be listed to allow for proper reconciliation as soon as possible after the support is provided.

With regards to events supported by SAMED Member Companies, the principles and criteria as set out in the Code i.e. Chapter 1: General criteria for events shall apply, irrespective of who organises the event.

## **Donations and “free of charge loans”**

The Code imposes strict limits on when, how and to whom Donations can be made. In general, only Charitable Donations can be made, and these, only to Charitable Organisations. This for example excludes hospitals from receiving Donations, unless they find themselves under “Financial Hardship”, which is defined very strictly and would likely not cover all situations of shortages of all kinds that hospitals and healthcare providers are currently experiencing.

In the current situation, and provided local laws and regulations allow such support Member Companies may provide Donations and/or “free of charge loans” to entities other than Charitable Organisations, including hospitals, healthcare systems, etc., subject to certain conditions, such as:

- “Free of charge loans” as referred to in this guidance, means the lending of products for a limited period (i.e. for the duration of the COVID-19 crisis) at no charge to the above described actors.
- All Donations, whether financial, capital equipment, products/consumables, services or/and software, that are motivated by the COVID-19 crisis should address an immediate need related to it and for a duration that relates to the need during the COVID-19 crisis.
- Even if it is possible to make Donations to different types of entities (as mentioned above, directly to HCOs for example), it is recommended to provide them to not for profit organizations or competent authorities adequately placed to assure support is provided based on the highest needs. In no case can donations be provided to individual HCPs.
- For Donations of equipment required to address an immediate need related to the COVID-19 crisis be provided, it is recommended, where possible and appropriate, to consider loan arrangements (including free of charge loans), properly documented with inclusion of clear retrieval criteria.

## **Staff-related support**

Member Companies may volunteer or be asked by HCOs to provide free-of-charge support through their own staff (i.e., in kind support provided by Member Company employees) in the HCO facilities and/or remotely due to staff shortages. This may include both qualified medical and paramedical staff as well as ad-hoc technical support.

Given the risks related to this support, and always in compliance with local laws and regulations (especially those regulating the practice of medicine, access to Theatres, etc), including internal HCO requirements, the request and/or staff support program must be approved and documented by the dedicated compliance/legal department of the company, and this only for a temporary time necessarily addressing a direct need related to the COVID 19 crisis.

Member companies are encouraged to liaise with their HR departments how to best handle this process and given the potential personal risks for the company staff involved, it is recommended to limit this support to volunteers.

All staff should be properly qualified for the requested services, and whenever possible, such support should be given to NGO's to avoid the perception of favouritism.

### **Payment arrangements**

When an HCO can demonstrate a critical financial situation, Member Companies may exceptionally decide to consider payment arrangements.

To this end, the relevant contracts should whenever possible be amended accordingly beforehand and each request must be thoroughly documented, with special emphasis in the underlying reasons.

In these situations, exceptional payment arrangements should be considered as a last resort and should only be granted as a last resort.

### **Company Organised Virtual Educational Events**

Due to the ongoing health crisis HCPs are unable to attend face to face Educational Events as they are critically needed in their workplaces, traveling is risky, and gatherings of people are either prohibited or attendance is heavily discouraged.

At the same time Medical Education is as critical as ever, if not more. Consequently, SAMED companies and Event organisers are focusing their Educational efforts on virtual events. The principles and criteria as set out in the Code i.e. Chapter 1: General criteria for events shall apply to virtual events supported in any way by member companies, irrespective of who organises the event.

## **Competition Law**

The Minister of Trade and Industry has recently provided for the exemption of certain healthcare products and services from the restrictions on competitors, and on customers and suppliers (in section 4 and 5 of the Competition Act) so as to allow providers of these goods and services to collaborate on the matters set out in the exemptions (as opposed to collude) in order to fight the Covid-19 pandemic. Members should acquaint themselves of these exemptions before collaborating in the provision of goods and services.