MedTech Europe Guidance Regarding Conduct during COVID-19 Crisis

In the current COVID-19 crisis medical device companies continue to prove support to healthcare professionals, healthcare organizations, healthcare systems and governments in order to fulfill the urgent needs. However, the local regulations and codes of conduct for the industry on relationship between the medical device companies and governmental organizations are still in force. Therefore, it is likely that some actions taken by the medical device companies in response to the crisis may contravene some of the requirements of the local regulations and codes of conduct.

The MedTech Europe which is the European trade association representing the medical technology industries, has its own codes of conduct named MedTech Europe Code of Ethical Business Practice ("MedTech Code"). On 27 March 2020, MedTech Europe Code Committee released a guidance titled COVID-19 Internal Compliance Guidance on Emergency Support ("Guidance") altering the MedTech Code during COVID-19 crisis. The Guidance aims at supporting MedTech companies' legal and/or compliance teams when considering emergency processes to fast-track requests related to the COVID-19 crisis to the benefit of the society as a whole while attempting to limit the inherent compliance risks.

With this Guidance, which supersedes some of the MedTech Code regulations, it is aimed to prevent the measures to be taken during the COVID-19 crisis from being counted as MedTech Code violations. However, the Guidance is only superseding those provisions when dealing with requests related to COVID-19, for the duration of the COVID-19 crisis and until the current COVID-19 crisis passes.

In addition, the Guidance is not intended to supersede any national laws or regulations or professional codes, including company codes and companies' internal policies. The local regulations are still in force and it should be noted that up until now there is not any temporary amendments made on the local regulations on medical devices in Turkey.

When dealing with any request related to COVID-19, the principles are set in the Guidance as follows;

- 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 or donations, decisions need to be made independent of the sales departments, or be made by leadership committees to ensure unbiased allocations.

Processes and Documentation

All kinds of support should be properly documented. In order to ensure appropriate documentation, an internal ad-hoc, fast track process can be considered. Where urgency requires acting before an internal process, all steps and approvals should be reconciled as soon as possible after the support is provided.

Donations and free of charge loans

In general, MedTech Code only permits charitable donations. During the COVID-19 crisis, the Guidance permits donations and/or free of charge loans to entities other than charitable organizations, including hospitals, healthcare systems, etc. However, still all donations should address an immediate need related to COVID-19 crisis, donations must not provided to individual HCPs and should generally be provided to not-for-profit organisations or competent authorities wherever possible. If equipment is being donated, the Guidance

recommends the use of loan arrangements, properly documented and including clear retrieval criteria.

Staff-related support

The request and/or staff support program related to COVID-19 crisis can be provided if only it is approved and documented by the compliance/legal department of the company, and this is only for a temporary time and necessarily addressing a direct need related to the COVID 19 crisis. Medical device companies should engage with their HR departments and the Guidance recommends limiting this support to volunteers. Whenever possible, such support should be given to nongovernmental organization to avoid the perception of favoritism.

Payment waivers

In case an HCO can demonstrate a critical financial situation, the medical device companies may exceptionally decide to consider payment waivers and the relevant contracts may be amended accordingly. According to the Guidance each request must be thoroughly documented, with special emphasis in the underlying reasons. The payment waivers should be considered as a last resort, and should only be granted exceptionally.

Employer notification and virtual educational events

Due to the ongoing COVID-19 crisis, HCPs are unable to attend face to face educational events. However, in response to the need of educational events in the ongoing circumstance, the Guidance regulates that invitations to HCPs to participate in Company Organized Virtual Educational Events do not require Employer Notification.