

MedTech Europe Code Committee¹ Guidance 15 March 2022

Compliance Guidance (“Guidance”) on Emergency Support for the Ukrainian Humanitarian Crisis

Objective & Introduction

This Guidance aims to support MedTech Europe Member Companies’ legal and/or compliance teams when considering emergency processes to fast-track requests related to the current humanitarian crisis in Ukraine and neighbouring countries while attempting to limit the inherent compliance risks of such processes.

This Guidance applies to any request related to support for people affected by the current crisis, whether the request is for support provided in Ukraine² itself, or for support provided in neighbouring countries sheltering displaced people.

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

Member Companies may be approached to provide support by different stakeholders in different formats 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; and
- payment waivers³ donations of financial support on a humanitarian basis to support Healthcare Organisations’ employment of temporary additional staff resources as needed, and purchase of additional products or services required through the Ukrainian humanitarian crisis.

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 examine legal and compliance considerations prior to offering their support such as, but not limited to, competition

¹ **About the Code Committee:** The Code Committee is MedTech Europe’s governance body in charge of deciding on matters of clarification of the Code. It is composed of representatives from the Ethics & Compliance Committee, the Legal Affairs Committee and the National Association Councils.

² Reference made for the avoidance of doubt, as Ukraine is not currently within the scope of the MedTech Europe Code of Ethical Business Practice.

³ Other payment arrangements used outside of crisis times can also be considered.

law, anti-corruption/antibribery 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 the MedTech Europe's Guidance on Placement of Capital Equipment⁴.

Guidance

Given the scale of the ongoing Ukrainian humanitarian crisis, the MedTech Europe Code Committee ("the Code Committee") acknowledges that some parts of this Guidance may contradict the MedTech Europe Code of Ethical Business Practice ("the Code")⁵ and therefore, this Guidance must be understood as superseding those provisions when dealing with requests related to said humanitarian crisis, **for the duration of the humanitarian crisis**.

In this sense, Member Companies must clearly document the link between the support provided and the Ukrainian humanitarian crisis, and when this link cannot be clearly established, or in 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 with any laws and regulations. As such, when dealing with any request related to the Ukrainian humanitarian crisis, 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 or Donations, decisions need to be made independent of the sales departments, or be made by leadership committees to ensure unbiased allocations

Processes & documentation

Under supervision of the Member 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 the Ukrainian humanitarian crisis as listed below.

⁴ The Guidance document is available in the Members' area/SharePoint, [here](#).

⁵ See, for example, regarding some aspects of Chapter 4: Grants and Charitable Donations.

Any kind 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.

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 may experience when dealing with HCOs inside a conflict zone or dealing with a sudden influx of displaced people in neighbouring countries.

In the current situation, and provided local laws and regulations allow such support Member Companies may provide Donations and/or “free of charge loans⁶” to entities other than Charitable Organisations, including hospitals, healthcare systems, etc., subject to certain conditions, such as:

- all Donations, whether financial, capital equipment, products/consumables, services or/and software, that are motivated by the Ukrainian humanitarian crisis should address an immediate need related to it and for a duration that relates to the need during the 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 organisations 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 Ukrainian humanitarian crisis to 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.

Payment waivers

Provided local laws and regulations allow for it, when an HCO can demonstrate a critical financial situation, Member Companies may exceptionally decide to consider payment waivers.

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, payment waivers should be considered as a last resort, and should only be granted exceptionally.

⁶ Please note that the terminology might differ on a country-by country basis. “Free of charge loans” as referred to in this Guidance means the lending of medtech products for a limited period of time (i.e., for the duration of the Ukrainian humanitarian crisis) at no charge to the above-described actors.