MedTech Europe Code of Ethical Business Practice 2022 Revision

Introduction

The MedTech Europe Code of Ethical Business Practice ("the Code") regulates all aspects of the medical technology ("medtech") industry's relationship with Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs), to ensure that all interactions are ethical and professional at all times and to maintain the trust of regulators, and – most importantly – patients.

The revision process

- 70+ people involved from 20+ companies divided in seven taskforces
- An entire year of work
- The entire Code was discussed & reviewed.

Main changes

- General clean-up & clarified language, old references removed, etc.
- No more reference to "gifts" – only "Promotional Items"
- New chapter on Distributors, consolidating all the existing rules in one place
- Virtual Events – modified several sections to include when Virtual Events may have different rules than in-person Events
- Clarification on the differences between Education Grants & commercial sponsorships
- New guidance in Annex on how to value in-kind Grants for transparency purposes
- New definitions in the Glossary (e.g. Delegate, Fair Market Value, Virtual Event, Proctorship, Preceptorship,…)
- Addition of "Collaborative Research"
- Consulting Arrangements chapter now applicable to HCOs & HCPs
- Re-organisation, and new look & feel.

Why a revision?

- The Code requires that a revision is launched every five years at the latest, or when required. The Code was approved in December 2015, and the revision was launched during the last quarter of 2020.
- Since December 2015, the MedTech Europe Code Committee and the Ethics and Compliance Committee have issued and updated a lot of guidance on practical aspects of the Code, or around areas that were not originally developed in detail. The medtech sector has evolved in these past years and the changes brought by the 2015 Code were so extensive that it required dozens of new and updated Q&As, as well as independent guidance documents.
- The Covid 19 pandemic has impacted all the types of interactions that medtech manufacturers have with HCPs. MedTech Europe has issued a compliance guidance document around Virtual Events, as well as specific rules to better manage the pandemic.
- The review aimed also at adding clarity and simplifying where possible. The revision process allowed extensive exchanges and debates among members of all aspects regulated by the Code to ensure wide level-playing field and broad buy-in.