Guidance on the interactions between the medical technology industry and Patients Organisations

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1. Introduction

Patient organisations (PO)[1] and the medical technology industry[2] share the aim of improving the awareness, prevention, diagnosis, management, and treatment of disease. It is desirable, therefore, that these two groups develop appropriate guidelines for interaction that lead to mutual trust and recognition of shared responsibilities. Both parties have a responsibility to ensure that their interactions are ethical and transparent, respect the independence of PO, and have the overriding purpose of improving patient outcomes. This paper aims to establish guidelines on how industry partners should act in such interactions.

2. Mission statement

Over the years, the healthcare environment has evolved to be more responsive to patient needs and decisions related to their health. By taking into account insights, expertise and feedback from PO, the medical technology industry has designed and developed more innovative and personalised diagnostics, technologies, services and solutions. Consequently, patient centricity has become a critical topic for the medical technology industry.

[1] Patient Organisation or Patients Groups (PO) are defined as not-for-profit organisations (including the umbrella organisations to which they belong), mainly composed of patients and/or caregivers, that represent and/or support the needs of patients and/or caregivers.

[2] Medical Technology refers to Medical Devices and In Vitro Diagnostics medical devices as defined in *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, as amended from time to time.*

Patients' quality of life can be significantly improved by the provision of timely, accurate, transparent, and meaningful information on prevention, diagnosis, management and treatment of diseases, products and services. By working to improve patient outcomes and create more sustainable healthcare systems, such information sharing advances the common aims of patients, the medical technology industry, the research environment, and healthcare systems more broadly.

MedTech Europe member companies recognise the experience and commitment of PO, and thus the value of dialogue locally and globally. PO accompany patients and their families, and often help them navigate the complex healthcare environment. PO are an essential stakeholder throughout the life cycle of medical technologies.

The medical technology industry and PO collaboration is instrumental in building up disease awareness, disseminating information and amplifying the voice of patients. Medical technology manufacturers may give support to a PO financially or by providing skills and expertise to advance such aims. MedTech Europe member companies acknowledge that any form of support given to PO can never be commercially motivated, nor perceived as such, where such support is provided.

3. Scope and definitions

The aim of this Guidance is to explain the rationale underpinning current interactions between the medtech industry and PO and propose principles on which such interactions should be based. In its Annex I, the Guidance outlines examples of types of collaboration that may exist throughout the life cycle of medical technologies.

Given the broad scope of the medical technology industry, this document is designed to offer principles that MedTech Europe member companies may use in developing their own guidance.

In this document, the reference to PO refers to patient groups, patient associations, and patients' advocacy groups. This document does not address relationships with individual patients. This document also does not address, nor would suggest any interference in, the critically important relationship between patients and their Healthcare Professionals[3] and other caretakers.

This document is not intended to supersede any applicable national laws or regulations.

[3] Please refer to the definition of Healthcare Professionals (HCPs) included in the MedTech Europe Code of Ethical Business Practice.

4. MedTech Europe Ethical Principles

An ethical framework protects the interactions between MedTech Europe member companies and PO. Such interactions should be based on the principles of Transparency, Independence, Integrity and Trust, and Equivalence.

a. Transparency

Transparency of the nature and objective of any collaboration allows for independent external scrutiny. All agreements between a MedTech Europe member company and a PO should therefore be in writing, properly documented and lay out the purpose and the desired outcome of the support provided by the MedTech Europe member companies.

Such collaborations must be in compliance with the law and any other applicable rules (e.g., Codes of Practice), including transparency and reporting rules where applicable. Additionally, both parties are encouraged to share with each other their respective existing guidelines on interactions between industry and PO. Any potential conflicts of interest[4] should be disclosed.

It is also recommended that both parties are transparent about the source of support for PO funding, where specific campaigns or activities are supported by MedTech Europe member companies (e.g., on respective websites, relevant campaign materials, annual reports, etc.).

b. Independence

PO independence in all aspects of decision-making, development of policies and external communications is essential to ensure their credibility.

The industry recognises support to PO as including campaigns and specific initiatives, as well as support for training of PO tailored to their specific needs.

Diversity of funding is preferable. MedTech Europe member companies should not seek to be the sole source of funding of a PO or PO activities.

MedTech Europe member companies should never propose or request the promotion or endorsement of a specific product or service.

[4] MedTech Europe Members are invited to refer to the principles of the MedTech Europe Code of Ethical Business Practice in the specific case where a Healthcare Professional is part of the governing structure of a PO for guidance on due diligence and conflict of interest management.

c. Integrity and Trust

Any communication coming out of a PO/medical technology industry collaboration needs to be neutral in tone, clear, accurate, balanced and fair. In any interaction, stakeholders bring their own perspectives, skills and experience. Such interactions should be based on mutual trust. All collaborations should have a legitimate need, including a clearly identified patient benefit, and should never be used to induce or encourage the use of MedTech Europe member companies' products or services, nor to seek confidential information.

The advancement of public health through improved disease awareness, prevention, diagnosis, management and treatment of diseases for the benefit of patients should prevail when supporting a PO.

d. Equivalence

Any support to a PO (i.e., whether in the form of a Grant or other types of support to PO capacity building) should be commensurate to the intended goal and should be fair market value.

5. Conclusive words

This Guidance and its Annex is intended to ensure a common understanding of how interactions between PO and medical technology manufacturers should be designed. At all times, any stakeholder should expect that this mutual collaboration is driven by the highest standards of respect, independence, transparency and integrity. Medtech Europe member companies believe these principles are an essential prerequisite to ensure patients have a strong voice in the improvement of patient outcomes and helping to make health systems more sustainable.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies, as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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Annex I

Examples of interactions between the medical technology companies and Patients Organisations

This Annex describes some examples of where Patients Organisations' (PO) and the medical technology industry's activities may intersect.

PO provide important feedback on real-world challenges and may share potential solutions to appropriate design or use of medical technology. Patient-led campaigns can help generate evidence-based and patient-friendly guidance on the appropriate use of medical technologies, which in turn can prevent misuse, reduce treatment errors and wastage, and foster patient education.

Ways in which PO can contribute to building mutual knowledge may include:

PATIENTS ORGANISATIONS' EXPERIENCE SHARING

- PO expertise in product and service design;
- PO feedback on experiences with medical technologies;
- Reporting on aspects such as safety and/or quality;
- Participation to advisory boards, ethics committees, expert panels;
- Surveys, studies, publications.

PATIENT EDUCATION / DISEASE AWARENESS-RAISING

- Support programmes / education of patients led by PO;
- PO disease awareness-raising via conferences, patient summits, media campaigns, online resources;
- Supporting patients on how to navigate healthcare systems, including access to care;
- Support patient voice and help reduce barriers to patient access.

INNOVATION AND R&D

- Collect evidence on unmet needs, sharing of knowledge on patient pathways, and/or improvement of quality of life;
- Patient recruitment to clinical trials or market research purposes;
- Innovations in public-private partnerships on digital health, services, integrated care driving patient empowerment, or self-management; Feedback on societal developments, such as sustainability.