

Working with the medical device industry: ethical professional practice

Clinical integrity, bias, fair market value, cost-effectiveness, access to funding, education, networking opportunities, improved patient outcomes. . . These are just some of the conflicting terms that influence our professional decision-making when we consider working with industry partners. Coupled with a lack of understanding, or indeed, the fear of getting it wrong, these dilemmas may deter individual clinicians from collaborating on projects in the commercial sector.

It is no secret that careful consideration is required if you are offered the opportunity to engage with a commercial organization. This is essential in order to prevent damaging repercussions occurring long after any interaction has taken place. However, skilled collaboration between healthcare professionals (HCPs) and commercial partners in the pharmaceutical and medical device arena is integral to the development of new drugs and devices that enhance patients' lives. There are also numerous benefits for clinicians in terms of access to continuing professional development, networking, and for some, the opportunity to transition into a professional role within the commercial sector.

Most HCPs will be familiar with the fact that pharmaceutical companies have been working to the Association of the British Pharmaceutical Industry (ABPI) Code of Practice since 1891, but it is only in recent years that medical device companies have had to review and change their interactions with clinicians and healthcare services. The MedTech Europe (MTE) Code of Ethical Business Practice came into force on 1 January 2017 for all existing commercial members (MTE 2015). The aim was to regulate medical device companies in the same way that pharmaceutical sector has been governed by the ABPI Code of Practice for the Pharmaceutical Industry (ABPI 2019).

While each has its individual nuances, both codes of practice regulate all aspects of the industry's relationship with HCPs and healthcare organizations (HCOs). This is in order to ensure that all interactions are ethical and professional at all times, and maintain the trust of regulators and, most importantly, patients.

Further changes mean that all medical device companies will be required to become members of MTE from 1 January 2020. These businesses will be required to abide by the relevant code, or face serious consequences in terms of fines and/or restrictions.

The ABPI Code of Practice for the Pharmaceutical Industry (ABPI 2019) and the MTE Code of Ethical Business Practice (MTE 2015) broadly cover the following activities, and stipulate how industry interacts with individual clinicians and HCOs:

- Industry must not make misleading claims in advertising in journals and direct mailshots, or online.
- All activity by company representatives, including any materials used by them, must not be misleading.
- The supply of samples must not interfere with the opportunity to offer choice.
- No inducements to prescribe, supply, administer, or buy or sell medicines or devices should be provided in any form, such as a gift, or an offer or promise of any benefit or bonus, whether in money or in kind.
- The payment of honoraria to professional speakers for company events/training must meet expectations of fair market value.
- The provision of hospitality must not be deemed as lavish.
- Promotional meetings must be held at a time and venue that is deemed appropriate.
- Companies must make publicly available financial details of any sponsorship of scientific and other meetings, including payment of delegate fees, travel and accommodation expenses for individuals.
- Patient information must not be misleading.

Medical devices, whether diagnostic or therapeutic, are an integral part of physiotherapy treatment. For many years, physiotherapists have worked with medical device companies in order to support product development and efficacy, and also to raise brand awareness. The MTE code has resulted in a dramatic change in the way that organizations can interact with HCPs, and as a result, all physiotherapists should be

equipped with an understanding of the code to help them make ethical decisions in practice. To ensure the integrity of the industry, MTE emphasizes that its members must: continue to respect the obligation of HCPs to make independent decisions regarding treatment; and safeguard the environment in which the interaction takes place. The MTE code provides guidance to support the following three aims (MTE 2015, p. 5):

- “Advancement of Medical Technologies
“The development of innovative medical devices, technologies and [*in vitro*] diagnostics and the improvement of existing products require collaboration between Member Companies and [HCPs] and [HCOs]. Innovation and creativity are essential to the development and evolution of medical technologies and/or related services.”
- “Safe and Effective Use of Medical Technology
“The safe and effective use of medical technology and related services requires Member Companies to offer [HCPs] and [HCOs] appropriate instruction, education, training, service and technical support.”
- “Research and Education
“Member Companies’ support of [*bona fide*] medical research and education [...] serves to enhance HCPs’ clinical skills and thereby contribute[s] to patient safety and increase[s] access to new technologies and/or related services.”

To achieve these aims, the code provides guidance on the interactions of member companies with both HCPs and HCOs, based upon the following five underlying principles (MTE 2015, pp. 5–6):

- *Image and perception* – “Member Companies should, at all times, consider the image and perception of the medical technology industry that will be projected to the public when interacting with [HCPs] and [HCOs]” (MTE 2015, p. 5). Likewise, HCPs should ensure that they consider what they are being asked to do before proceeding.
- *Separation* – “Interaction between industry and [HCPs/HCOs] must not be misused to influence through undue or improper advantages, [or] purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of Member Companies’ products” (MTE 2015, p. 5).

Healthcare professionals should be mindful of this when entering into any activity with an industry partner, and ensure that they are comfortable with everything that they are being asked to do before proceeding.

- *Transparency* – “Interaction between industry and [HCPs/HCOs] must be transparent and comply with national and local laws, regulations or professional codes of conduct” (MTE 2015, p. 6). Healthcare professionals should always consider what the implications are for their professional integrity if the activity goes ahead, or is uncovered at a later date.
- *Equivalence* – “Where [HCPs] are engaged by a Member Company to perform a service for or on behalf of a Member Company, the remuneration paid by the Member Company must be commensurate with, and represent[,] a fair market value for [...] the services performed by the [HCP]” (MTE 2015, p. 6). Individual HCPs should be aware of this when negotiating rates of pay, as well as the need to gain written approval from their employer/manager.
- *Documentation* – “For interactions between a Member Company and a [HCP], such as where services are performed by a [HCP] for or on behalf of a Member Company, there must be a written agreement setting out, [*inter alia*], the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the Member Company” (MTE 2015, p. 6). Healthcare professionals should be aware that HCOs are required to maintain this information on file, and HCPs should also keep copies of documentation relating to any services provided on file.

The potential sanctions available to the APBI or MTE compliance panels and member associations’ national panels must be proportionate to the infringement, predictable and act as a deterrent. Commensurate with the seriousness and/or persistence of the breach, such sanctions may range from (MTE 2015, p. 48):

- “[a] written reprimand;
- “[t]he requirement that the offender takes steps to conform with the national and/or the [MTE] code(s) (specific steps may be specified in whole or in part, and may be subject to time limits);
- “[t]he inspection and audit by a third party (at the offender’s cost and expense) of the offender’s relevant compliance systems;

- “[t]he requirement that the offender recovers items given in connection with the promotion of products and/or to issue a customer communication regarding future corrective practice;
- “[t]he requirement that the offender publishes or otherwise disseminates corrective or clarificatory information or statements;
- “[t]he prohibition against offending company representative(s) standing for elected office within the institutions of [the] Member Association and/or [MTE];
- “[r]ecommendation to suspend the offending company – with specific time limit and detail on conditions of ‘re-entry’ – of membership of the Member Association and/or [MTE]; [and]
- “[r]ecommendation to expel the offending company from membership of the Member Association and/or [MTE];
- “[u]p to publication of any decisions or sanctions imposed upon the offender.”

If clinicians have been involved, their name and details of their participation in the breach may also be published.

Finally, it is worth remembering that the APBI and MTE codes have not been implemented to stop innovation and prevent shared best practice. These are designed to ensure that all interactions between industry and healthcare professionals

are ethical, and protect the best interest of all parties concerned.

In reality, there is little to fear and much to gain for clinicians who collaborate with industry, as long as anything they do could stand up to the “*Daily Mail* test” now or in the future. If your relationship with the commercial sector hit the headlines, would you be comfortable with this in your professional capacity? If your answer is “yes”, then it is unlikely that you have anything to worry about, but if you have the slightest doubt, then you should seek advice before proceeding. A quick call to your line manager or the Chartered Society of Physiotherapy now could save a great deal of angst later.

Debbie Gordon

*Chartered Physiotherapist and Independent
Marketing Consultant*

London

UK

E-mail: dg@mehealthcareconsultancy.com

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