Original article

Healthcare professionals and interactions with the medical devices industry

ABSTRACT

Compliance laws for healthcare professional practices are evolving continuously. It can therefore remain difficult to remain abreast of all laws that apply across all countries. This paper serves as guidance for best practice for healthcare professionals (HCPs) working alongside the medical devices industry.

Keywords Compliance, medical devices, nursing profession, ostomy, ethics, industry, healthcare professionals

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INTRODUCTION

Engaging with product manufacturers and suppliers from within the medical devices industry should, at its best, be a symbiotic relationship where both the healthcare professional (HCP) and the industry representative – henceforth referred to as Industry – derive mutual, yet appropriate, benefits. This relationship should be driven by the ultimate objective of improving patient outcomes. However, this affiliation can be challenging when ensuring objectivity and compliance for both Industry and the HCP. For example, recent global changes of compliance laws designed to govern these affiliations can make it difficult to ensure all parties remain compliant. However, the overall trend is toward transparency by Industry on any such interactions, and these same considerations are increasingly becoming the focus of employers of HCPs as well as the HCP professional bodies.

This paper focuses on global and local laws, codes and market trends in compliance to better inform and protect the HCP. By being more aware of the compliance requirements and legal ramifications when interacting with Industry, the HCP will be in a better position to navigate complex interactions that may place them at risk.

Paris Purnell
Senior Manager, Clinical Education
Hollister Incorporated, Illinois, USA
Email paris.purnell@hollister.com

WHAT IS COMPLIANCE?

Compliance involves a broad series of interactions with HCPs and includes activities such as the promotion of advancements in medical technologies, enhancements in the safe and effective use of medical technologies, research and education activities, and fostering of charitable donations and giving[1]. For the purposes of this paper, 'compliance' is used to describe the ethical code where the first duty of the HCP is to act in the best interests of the patient by working through beneficial relationships with industry in a transparent and ethical manner. Additionally, while the descriptor for a HCP covers most multidisciplinary healthcare workers, this paper refers specifically to the nursing HCPs prescribing medical devices for patients such as ostomy, wound care and continence as this is the audience for this journal. Lastly, medical devices are often highly dependent upon 'hands on' HCP interaction from beginning to end, unlike drugs and biologics which act on the human body by pharmacological, immunological or metabolic means[2]. This often requires Industry to provide HCPs with appropriate instruction, education and training.

As described, compliance laws regarding the interactions of HCPs with Industry are continuously changing. Compounding this challenge, are the variances in the compliance laws by country and sometimes even within that country's boundaries. Ensuring the HCP is cognisant of the potential pitfalls that may not be apparent when contracting with a manufacturer for either a service or another activity – such as sponsorship – are important considerations. Given the changing face of compliance globally – particularly around some commercial activities that might be considered legal (for now) but not

necessarily ethical – it is a timely and worthy discussion to guide the HCP in protecting themselves against potential risk.

INTERNATIONAL AND LOCAL COMPLIANCE BODIES / LOCAL TRADE ASSOCIATIONS

There are several international compliance bodies (Figure 1) exerting influences on local Industry and HCP interactions. The larger bodies include AdvaMed (mainly influencing US, Chinese and Latin America activities and companies), MedTech Europe (formerly 'EucoMed', covering Europe), APACMed (covering Asia Pacific), and MecoMed (covering the Middle East).

Most countries also have compliance bodies locally which, in turn, often ascribe to at least one of these larger governance bodies. These larger bodies generally set the core principles and ethics that local bodies would engage with as members of the parent body. There are far too many local bodies from a global perspective to create an exhaustive list in this paper. However, from a nursing perspective, there are various registration boards for registered nurses/midwives that operate within each country. These boards each have their own code of ethics and professional standards that influence local practices. For example, Australian nurses ascribe to Australian registration boards such as the Australian Health Practitioners Regulatory Authority and Nursing and Midwifery Board of Australia (NMBA)[3], the Wound Ostomy and Continence Nurses Society (WOCN)[4] and, of course, the WCET[5].

Medical devices are also regulated by local governmental agencies which in turn have their own codes. As one example, the Medical Technology Association of Australia (MTAA) is the governing body regarding compliance for the medical devices industry that includes ostomy products in Australia which has strict codes of conduct and laws regarding interactions between HCPs and Industry. According to the MTAA website[6]:

> *In all dealings with Healthcare Professionals, a Company must undertake ethical business practices and socially responsible Industry conduct and must not use any inappropriate inducement or offer any personal benefit or advantage in order to Promote or encourage the use of its products.*

This basic definition is a concise summary of what Industry should be following in terms of ethical practices in working with any HCP. One key takeaway message from this simple narrative is the term 'inducement'. Products must be prescribed on clinical application and suitability. Product usage should not be based upon a 'quid pro quo' basis where the HCP and the company are deriving either singular or mutual benefits. This is commonly referred to as 'corruption'.

As such, while local laws and customs often come into play, an important consideration when the HCP wishes to engage with Industry is to err on the side of caution and follow the rules of the compliance body which are the most stringent. As an example, while some manufacturers in the EU may not necessarily fully ascribe to these bodies, from 2020 MedTech Europe has determined that ALL local trade associations must abide by stricter MedTech Guidelines[7]. These enforceable ethical standards will be placed on Industry to come into line with all other already compliant manufacturers and service providers.

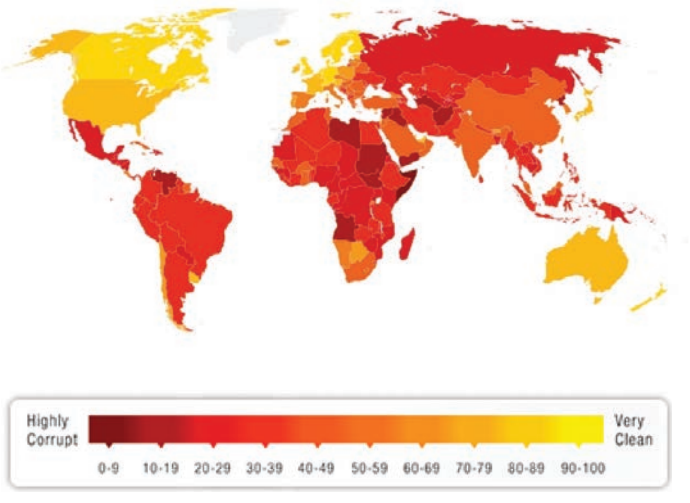
CORRUPTION AND SPONSORSHIP

However, laws are constantly changing regarding corruption and sponsorship. Transparency International has developed and mapped the perception of corruption indices across the globe concerning all industries and governments, with darker colours illustrating the perception of higher levels of corruption[8]; the more yellow (lighter colour), the perception is cleaner and freer from corruption (Figure 2). Yet, while it is good to obtain such a standard, there is an inference that additional scrutiny is required to maintain these standards. This means more oversight into interactions will be assessed. Unfortunately, in recent years, the majority of countries are making little or no progress in ending corruption, while further analysis shows journalists and activists in corrupt countries risk their lives each day in an effort to speak out[8].

Previously, direct sponsorship usually involved the selection of the HCP by the Industry and direct payment by Industry to the HCP, their institution, or a third-party vendor for the HCP's travel, lodging, meals, other transportation expenses,

Figure 1. International compliance bodies.

Figure 2. Corruption perceptions indices across the globe[8].



conference registration fees or other costs associated with a third-party educational conferences such as those hosted by the European Council of Enterostomal Therapy (ECET), the Society of Urologic Nurses and Associates (SUNA), the Symposium on Advanced Wound Care (SAWC), WOCN or WCET conferences[2]. This is being, or has already been, phased out in many countries; MedTech Europe illustrates where direct sponsorship is forbidden[7] (Figure 3).

Additionally, the concept of direct sponsorship can mean arrangements where Industry selects or influences the selection of a specific HCP through their institution or professional body, or was provided with advance knowledge of the identity of a specific HCP who might benefit directly from Industry funding[2]. This practice is an 'indirect' method of achieving the same objective of direct sponsorship whereby deliberate sponsorship of a specific HCP still occurs. As such, this is also not permissible. As a consequence, the funding must be indirect via an educational grant. MedTech Europe creates another level by enforcing some transparency requirements for all educational grants provided by the industry to healthcare organizations. Access to the transparency report is available on: https://www.ethicalmedtech.eu/transparent-medtech/

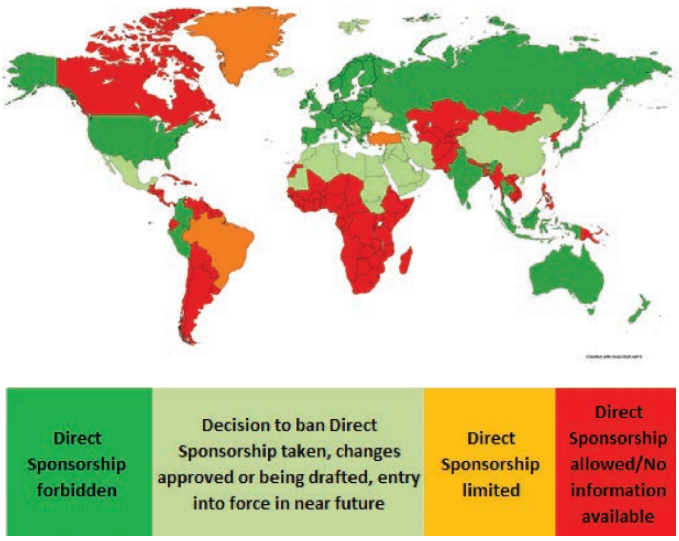
GENERAL RULES OF ENGAGEMENT FOR THE HCP WITH INDUSTRY

There are several topics for discussion around some rules of engagement for the HCP with Industry, including entertainment, hospitality, event venues and location, travel, contracting, remuneration / compensation, transparency, gifts and samples. Each of the following discussions regarding these outline global compliance standards.

Entertainment

It is prohibited for Industry to organise Industry events – including social, sporting and/or leisure activity or other forms of entertainment – that has no value in terms of education, for example, providing a famous singer at an event, taking nurses to a spa treatment day as an example of managing patients' skin issues, creating fun artworks/animals using specific medical devices that have no relation to intended use etc. It is also forbidden for Industry to support such entertainment when part of a third-party event, for example live music, sport event, dancing contest. However, there is some tolerance in a third-party event when such entertainment is outside of the scientific / educational programme, is paid for by the HCP, does not dominate / interfere with the educational programme, and is not the main attraction.

Figure 3. Countries where direct sponsorship is either allowed or forbidden[7].



Hospitality

Hospitality in this sense relates to meals and/or accommodation. Accommodation should be subordinate in time, with no extensions of stay unless paid for by the HCP. It should only be for the time of the event/meeting that is necessary. Some of these rules are often determined by type of meeting being arranged, for example if the meeting is classified as 'active' or 'passive'. Active events are where the HCP is expected to actively participate and contribute in the meeting, for example a Clinical Advisory Board or Consensus Panel. In these types of events, the HCP is in essence 'working' and it is expected that costs incurred for attending the meeting would be reimbursed by Industry. In contrast, passive events are where Industry is presenting to the audience with no reciprocal interaction being required by the HCP. Regarding product promotional events that are organised by Industry – even if they are educational, for example the launch of a new product – no transportation nor hotel fees should be supported. The HCP is expected to cover these costs themselves as this is considered a passive event. However, modest meals at a passive educational event are permitted.

Generally, the meals and accommodation should focus to the purpose of the event and should be seemed as reasonable, for example such as what the HCP would expect to pay by themselves. Recommendations around these values have been determined by trade associations on local laws, and these have been set up in most countries in the world. Maximum amounts for lunches and dinners have been outlined for every country – the rule to apply is generally that of the law governing the hospitality of the country where the HCP is licensed to practise.

Event venues and locations

Industry should respect the following criteria when selecting a venue for an event.

- Perceived image – how it could be seen by the public.
- Centrality – whether it is centrally located for the participants.
- Ease of access – whether it has easy transportation, is close to airport/venue. A recognised scientific or business centre is preferred.
- Time of year – ideally this should not be associated to a tourist season.
- Adapted to the purpose of the meeting – are the rooms appropriate for their intended use.

An event location where the meeting purpose appears secondary to the location is seen as an inducement for the HCP to attend based on the location and not the content or objective of the meeting. As such, event locations should not be lavish such as five-star, golf facilities, spa retreats etc. If the HCP notices the event venue seems inappropriate (for example an amusement park or a retreat), the HCP should reconsider the event.

Travel

When Industry is arranging travel, it must be directly linked to the meeting length and cannot be extended for the purpose of sightseeing / family visits etc. Industry cannot cover a period of stay beyond the official duration of the event.

Travel is linked only to the purpose of the meeting and, like hospitality, should be modest and reasonable – no business / first class air tickets. Related travel expenses for active meetings such as parking, train fares etc. are reimbursable but should be agreed upon prior to the expense.

Contracting

Industry may engage HCPs as consultants and advisors to provide bona fide consulting and other services, including research studies, participation on ostomy/wound advisory boards, presentations at Industry educational events, and new product development. In selecting the HCP, there should be appropriate criteria that includes:

- Legitimate interest – Industry should not contract with a HCP 'just in case' or if there is a lack of in-house competencies.
- Appropriate qualifications – the HCP should be technically and scientifically qualified, with the right competencies to achieve the assignment. Industry should collect a CV for documentation and to justify any compensation.
- No financial gain – selection should be detached from sales to avoid any influence.

Contracts with the HCP shall not be contingent in any way on the prospective consultant's past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of the contractor's products or services. In other words, there is no 'quid pro quo' expectation from Industry that the HCP will use/prescribe their products.

Contracts must involve appropriate documentation to justify the compensation – if any – paid to the HCP. MedTech Europe and AdvaMed have specific requirements for written agreements with the HCP[1,7]. The contracts also protect Industry by ensuring confidentiality on projects is maintained for new products or strategies so they are not shared with competition. Industry also maintains rights to use the material / research / studies developed by the HCP during the assignment. Lastly, contracts must provide transparency. They ensure information of, and to, the HCP's employer on the existence of the contract, state exactly what the assignment is, and how much compensation (if any) is paid to the HCP.

Remuneration / compensation

When compensating the HCP for their services, reasonable and fair market value (FMV) compensation should be aligned with the market value for that HCP and the type of service. Guidance on FMV should be sought with compliance officers or the local HCP's Association, for example the NMBA. In addition, documentation of the type and the length of service with associated remuneration is to be captured and signed off by both Industry and the HCP prior to the event occurring.

Transparency

Before engaging with Industry, as a best practice it is strongly suggested that the HPC should gain approval / notification of the HCP's employer. While not always mandatory, this transparency covers both parties if there arises any questions regarding conflicts of interest. The employer of the HCP should receive full disclosure of the purpose and scope of consultancy agreement. Additionally, all Industry contracts should contain a clause on the obligation of the HCP to notify the existence of the agreement to their hierarchy. It is prudent to check local requirements.

Gifts

In principle, it is prohibited by Industry to provide gifts to the HCP. Local customs may need examining to determine if this is still permissible. For example, in Japan and Thailand there is frequently an expectation of gifts of thanks. These should not be excessive in nature and should not create any expectations of quid pro quo. Local customs and laws may come into play; however, it is recommended to check with a compliance officer prior to engaging in any gifting activities if there is any ambiguity. In some countries, it is now no longer permissible to give birthday or bereavement cards or flowers, and local laws should be evaluated prior to exploring the potential for providing such gifts.

Industry may provide inexpensive educational items and/or gifts in exceptional circumstances, in accordance with local laws, regulations and industry and professional codes of conduct of the country where the HCP is licensed. Excluded 'educational' items are DVD players for playing educational movies, or cameras for wound care as these can be used for other purposes. Acceptable educational gifts can be purely educational (medical) book vouchers, registration to third-party events or educational courses, although these are paid to the third-party only – no cash should be paid direct to any HCP. Again, full transparency is required and documentation should be provided to cover both parties.

Samples

Industry may provide products as samples at no charge in order to enable the HCP to evaluate and/or familiarise themselves with the safe, effective and appropriate use and functionality of the product. This will allow HCPs to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future. Provision of samples must not improperly reward, induce and/or encourage HCPs to purchase, lease, recommend, prescribe, use, supply nor procure their products or services.

Any offer and/or supply of samples shall always be done in full compliance with applicable national laws, regulations and industry and professional codes of conduct.

Recent US and European laws, as well as MedTech guidelines in the EU[7], require the maintenance of appropriate records in relation to the provision of samples to HCPs, for example recording proof of delivery of samples. These are now to be clearly recorded in the books on a no-charge basis, and this and other conditions applicable for the supply of such samples must be clearly disclosed – in writing and at the time of supply – to HCPs.

The concern is the over-supply of samples (dumping) that may be perceived as an inducement to use the certain products. Samples, as described, should be modest. Anecdotally, for the ostomy Industry, there appears to be an oversupply (stocking) of products at many institutions instead of these institutions purchasing. This practice is possibly in need of further scrutiny.

RED FLAGS – WARNINGS

The HCP should become familiar before considering interactions with Industry across multiple issues. There are certain common 'red flags' that should create alerts in the mind of the HCP that include situations where there is:

- Wording or phrasing with 'win', 'gift', or 'prize'.
- No professional educational relationship associated with the benefit.
- Entertainment.
- A submission for 'competitions' judged only by Industry manufacturers (no third-party).
- A value which is high in comparison with the effort required.
- Anything which seems 'too good to be true'.
- Excessive sampling (dumping) of products.

GENERAL RULES OF THUMB FOR PROTECTING THE HCP

- Obtain the full rules of engagement from the device manufacturer.
- Review it with your existing employer's audit committee / managers.
- Check with your professional body, both local and national.
- Review any available guidelines, both local, national or institutional.
- If in doubt, don't do anything.
- Consider the 'optics' – how might the interaction look if it appeared in the news? Is this clean and free from potential misunderstanding?

CONCLUSION

There are risks for the HCP when engaging with Industry, and rules and laws are constantly changing. It is difficult to remain ahead and informed of these continuous changes; however, this paper aims to raise awareness of this ever-changing landscape. For the HCP, it is a wise idea to check and follow the rules of engagement, observe the red flags and, if there are any doubts, to err on the side of caution and simply not engage. Ultimately, the goal for each party is to improve patient outcomes and create a prosperous dynamic that is compliant. Interactions between Industry and the HCP are inevitable, but if the relationship is open, honest and transparent, with clear rules of engagement and oversight, these relationships can be extremely fruitful for each party.

DISCLAIMER

Laws from regulatory bodies are frequently updated. At the time of print, this is a fair assumption of current practices. As always, it remains advisable to seek further guidance from the HCP local regulatory body or employer if there is any doubt before any action/s is taken.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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