In this issue: Ethics in laboratory medicine

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How does the MedTech Europe Code of Ethical Business Practice affect the activities of professional societies in laboratory medicine?

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ABSTRACT

The MedTech Europe Code of Ethical Business Practice came into effect on 1 January 2018. It was created by the medical technology industry. It addresses the importance of fair management of educational grants: public disclosure of provided educational grants, compliance of conferences with the Conference Vetting System; allocation of grants to healthcare organizations (HCOs) but not to the healthcare professionals (HCPs); the need for written contracts with HCOs, etc. As a National Society and member of IFCC and EFLM, the Lithuanian Society of Laboratory Medicine (LLMD) has created a fund dedicated to the continuous professional development of LLMD member HCPs. The fund, as an instrument for the ethical use of money, corresponds to the principles of the MedTech Code of Ethical Business Practice and is an example on how HCOs can implement it to ensure ethical communication between the IVD (In Vitro Diagnostics) industry,

HCOs and their member HCPs. Scarce data exists on the level of MedTech acceptance and implementation among HCOs and HCPs, thus more effort has to be made to better communicate and consequently improve fair use of the funds received from the industry, and to improve the ethical behavior of HCPs.

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CHANGE IS HERE

Diagnostic companies all around the Europe are no longer allowed to pay specialists in laboratory medicine directly to attend third-party educational conferences. Since 2015, when medical technology companies joined together to form the alliance we know today as MedTech Europe, the world of continuous professional development has changed dramatically. The changing situation affected all healthcare professionals (HCPs) and healthcare organizations (HCOs), including those involved in laboratory medicine. The pharmaceutical industry did not stop direct sponsorship, but rather continued it while agreeing to declare all relevant relations. But MedTech Europe went a huge step further, declaring that "…there are certain conflicts of interest that maybe we should prohibit. Transparency is not enough," (1) and started to foster the highest ethical standards in the medical technology industry, including for all activities related to training, medical education and professional relationships with HCPs (2).

It is now undoubtedly clear that not only the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) and their National Societies (NSs), but also every individual laboratory medicine specialist should be aware of the importance of the ethical issues described in the MedTech Code (2, 3). Briefly, the MedTech Code sets stronger rules for educational grants: 1) medical technology companies should publicly disclose educational grants provided to HCOs, ensuring increased transparency of the funds allocated to medical education; 2) conferences supported by these companies must comply with the Conference Vetting System; 3) companies are only able to provide grants, charitable donations, scholarships or fellowships to HCOs but never to individuals; 4) companies are able to define the category of HCPs eligible for financial support under the grant but not to choose individual HCPs; 5) companies are required to sign a written contract with HCOs setting out the terms and conditions for grants, charitable donations, scholarships or fellowships; and 6) companies must establish an internal and independent process based on objective criteria to review grant requests (4).

TWO LEVELS OF INTERACTION

MedTech Europe focuses on several levels of interactions between Member companies, HCPs and HCOs. The individual level of interaction with HCPs covers two areas of interest. First, HCPs are interested in participating in scientific meetings, conferences or other third-party-organized events. Secondly, HCPs might be involved as consultants and advisors to provide bona fide consulting and other services, including but not limited to research, inclusion on advisory boards, presentations at Company Events and product development (2). The latter form of involvement might be remunerated by the IVD industry and is subject to clear rules to be followed by the industry and by HCPs themselves. The other level of interactions is organizational and requires that HCOs set their rules and criteria for ethical organization of scientific events (5) and ethically support their member HCPs who participate in those events. The focus of this article is on individual HCPs who are in need of financial support for the purposes of training and continuous professional development, and also

HCOs who are expected to apply high ethical standards for the aforementioned interactions.

It is almost impossible to judge how HCOs behave and which practices they apply without conducting a properly organized survey. The first attempt to investigate the landscape of MedTech acceptance and implementation among European professional societies of laboratory medicine was carried out by the Committee on Education and Training (C-ET) and the Working Group for Congresses and Postgraduate Education (WG-CPE) at EFLM (3). The results of the surveys conducted are heterogeneous but provide interesting ethical aspects, which should be discussed by each HCO and transferred to their HCPs. The authors found that there still are some National Societies who have not yet adopted the MedTech Europe Code, thereby raising the risk of direct financing of HCPs by the IVD industry. The survey results have shown that even up to one fifth of respondents always use direct IVD financing. Detailed survey results and outcomes can be found in the EFLM journal Clinical Chemistry and Laboratory Medicine (3). Meanwhile the Legal and Compliance team at MedTech Europe have documented in their Compliance Report 2019 a significant increase in the percentage of National Associations that have banned direct sponsorship (from 13 % in 2017 to 95 % in 2019) (6).

AN EXAMPLE OF ONE SOCIETY

As a National Society and member of the IFCC and EFLM, the Lithuanian Society of Laboratory Medicine (LLMD) felt obliged to act fairly. Thus, for the purposes of compliance with the MedTech Europe Code of Ethical Business Practice, the LLMD implemented a special measure in 2017 – the fund for continuous professional development of the LLMD member HCPs. It has determined the rules for the ethical use of the fund. By way of these rules the LLMD defines the procedures for the organization of scientific conferences and support of the continuous professional development of its member HCPs (specialists in laboratory medicine). The purpose of the fund is the financing of scientific conferences organized by the LLMD (LLMD events) and the financing of the expenses of LLMD member HCPs dedicated to their continuous professional development in external conferences not organized by the LLMD (external events). As a beneficiary, the LLMD accumulates resources in the Fund as educational financial support/sponsorship from support givers according to the national law of charity and sponsorship. The Meeting of the Board members of the LLMD plans the usage of the Fund yearly and makes plans for LLMD events and external events to be funded.

The funds are most frequently used to provide LLMD member HCPs with the opportunity to participate in external (third-party-organized) events, which are normally costly and beyond the financial means of LLMD members. However, it is not possible to grant funding to all applicants, and so the LLMD has listed the priorities according to which its member HCPs are funded. First, funds are allocated if an LLMD member HCP gives an oral presentation, has provided an abstract and/or poster, is a member of the scientific/organizing committee or the chair of a scientific event. Secondly, an LLMD member HCP is granted funding if he or she participates as a corresponding member, national representative or a member of the committee/working group of the IFCC, EFLM or another subspecialty professional society. Following the aforementioned individuals, priority is then given to LLMD member HCPs who are members of working groups created by the Ministry of Health of the Republic of Lithuania and young scientists under the age of 35 years, and who in the past 12 months have published at least one article in the national journal of the LLMD (Laboratorine medicina)

or any other peer-reviewed journal. Finally, any other LLMD member HCPs who have submitted a written application for financial support are considered.

Only certain expenses can be covered by the Fund. When an applicant is selected for an external scientific event, only 1) the registration fee (preferably an early bird registration fee), 2) accommodation expenses (where the external event takes place abroad and the cost of the accommodation per night does not exceed the amount defined by the relevant Order of the Minister for Finance) and 3) travel expenses (only standard/economy flight tickets, or bus/train tickets if flights to the destination city are unavailable) are eligible for funding. Also, pursuant to the MedTech Code, the LLMD does not pay for 1) participation in social events (i.e. gala dinners), 2) taxis, public transport or other transportation services at the destination city where the external event is held, 3) personal expenses of LLMD member HCPs, 4) expenses of persons accompanying LLMD member HCPs, 5) travel insurance and 6) daily allowances. These must be covered by the applicant himself/herself.

Funding of the LLMD's HCPs was not always consistent before the implementation of the funding rules. In 2012, it was discovered that a substantial number of applications for educational grants from the LLMD were coming indirectly from IVD companies or their national distributors. The IVD industry was selecting HCPs to be funded and granted funds to the LLMD. After implementation of the rules for ethical funding, the situation changed. In our opinion for the better, because even if the IVD industry is interested in certain HCPs, the LLMD would decide itself whether or not the HCP in question complies with the rules, and then finally allocate funds irrespective of the wishes of the IVD industry.

From 2013 to 2019, the LLMD was able to identify 19 attempts at targeted funding of LLMD member HCPs (Table 1) and was able to successfully change their funding policy to block these attempts. The increasing number of detected targeted funding attempts reflects the Society's efforts to ensure fair funding and successful implementation of the MedTech Europe Code of Ethical Business Practice. Interestingly, all targeted HCP funding attempts were performed by the distributors of IVD companies, acting as independent legal entities, which work as distributors of several IVD companies (brands) at once. This creates an impression that IVD companies (original brands) do not pay enough attention to the compliance of their distributors. Thus HCOs (in this particular case the LLMD itself) have to act fairly and start communicating with irresponsible entities (national distributors) within the IVD industry chain.

In terms of internal LLMD events, the LLMD has experience in organizing international congresses in the field of laboratory medicine, namely BALM (Baltic Congress of Laboratory medicine). One of the last congresses took place in 2018 in Vilnius (Lithuania), which was already compliant with the MedTech Europe Code's General Criteria for Events and successfully approved in the Conference Vetting System. All 6 criteria were met successfully: scientific programme, geographic location, venue, hospitality, registration package benefits and communication (5), according to the IFCC's guidance and recommendations (7).

FUTURE PERSPECTIVES

The diversity of the EFLM survey results (3) and the lack of communication between the IVD industry and leading HCOs (8) leads to several questions for the future of conferences and their attendance. Will there be any provisions and changes in the MedTech Code? Will HCPs

Table 1 Overview of educational grants at the Lithuanian Society of Laboratory Medicine (LLMD) in 2013-2019

Financial year	Number of funded HCPs	Number of external events	Average expenses per HCP, EUR	Number of agreements with IVD companies or their distributors	Number of blocked targeted HCP funding attempts
2013	33	16	1171	14	0
2014	37	15	1253	30	0
	107	16 (including BALM)	628		
2015	75	19	1372	31	1
2016	33	17	855	22	3
	110	18 (including BALM)	449		
2017	64	19	967	9	5
2018	36	14	1114	23	7
	138	22 (including BALM and 7 other small national events)	447		
2019	58	17	1165	11	3

Abbreviations in the table: *BALM – Baltic Congress of Laboratory Medicine (usually involving smaller registration fees and less travel expenses); IVD – in vitro diagnostics; HCP – healthcare professional.*

and HCOs achieve full compliance? Will there be less attendees at congresses and conferences? It seems that the Code is not going to change, and our profession has to live with it. Still, we have to put more effort into achieving better communication between the IVD industry and HCPs in order to guarantee improved and fair use of the funds received from the industry, and we must also redouble efforts dedicated to organizing and attending scientific events (3).There is a need to follow up on C-ET and WG-CPE surveys in terms of how countries have managed to implement the principles of the Code or to improve the ethical behavior of their HCPs, as well as in terms of whether individual HCPs become more conscientious (9) in maintaining fair interactions with the IVD industry.

The year 2020 has thus far proven challenging to everyone involved in postgraduate training and organization of scientific events due to the global COVID-19 pandemic. Many highly valuable congresses and conferences have had to be cancelled or postponed for a long time, while others have been held virtually in order to give HCPs the option to attend events online, sometimes even without any registration fee. This format is an option for the future of scientific events and has to be considered by HCOs and event organizers.

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