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LETTER TO THE EDITOR

The Ongoing Challenges Faced by Providers of CME-CPD in Europe

Monica Ghidinelli [a], Eugene Pozniak [b], Celeste Kolanko [c] and Sophie Wilson [d]

[a]AO Foundation, AO Education Institute, Duebendorf, Switzerland; [b]Siyemi Learning, Manchester, UK; [c]Liberum IME, London, UK; [d]International Medical Press, London, UK

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Dear Editor

We write on behalf of the Good CME Practice group (gCMEp), to draw attention to the emergence of what we think is a serious problem in European CME-CPD that the group first identified as a possible issue in 2011, when we wrote an Open Letter to both the European Accreditation Council for CME of the European Union of Medical Specialists (UEMS-EACCME) and European Federation of Pharmaceutical Industries and Associations (EFPIA) [1]. In that letter, we identified the potential problem that "in the absence of clear and consistent guidance from accreditation agencies" the European continuing medical education (CME) providers would be faced with "conflicting requirements for independence, accreditation and use of funding" [1].

Since the start of 2023, we are seeing a clear manifestation of this with the consequence that healthcare professionals are being excluded from accredited CME. Some pharmaceutical companies, funding international accredited CME-CPD, are instructing education providers to whom they have provided funding, to exclude or block healthcare professionals practising in the UK from attending or viewing educational activities they have supported. We are aware of British doctors being "geoblocked" from international enduring education, being excluded from invitations to CME accredited meetings, symposia and other pharma-funded education. Added to this, some pharma companies and education providers are even withdrawing from using accreditation standards, as they do not promote or define independence from industry control.

We are concerned that this may be the start of a domino effect across Europe, where accreditation standards are not aligned with the changing anti-corruption legislation and accounting practices, especially as industry changes their practices in order to avoid serious breaches. If there is a continued misalignment of compliance requirements, we foresee a situation where international CME-CPD, whether or not industry funding is involved, will discriminate between countries, and ultimately the funding of accredited CME-CPD activities for the professional education providers, as well as medical societies, hospitals and others, will fall into decline. This may lead to a reduction in accredited activities for healthcare professionals and ultimately risks impacting the health of patients.

The Accreditors and Regulators

We appreciate the critically important role of the accreditors in Europe, and as educators we work with them to review and certify our education as being of appropriate quality and, ideally, independent of control by industry. The rules and requirements, however, in some cases have not evolved to keep pace with the changes in national and European anti-corruption laws, taxation and accounting practices, and the resulting amended industry regulations.

The most important challenge is the evolution of the definitions of independence in medical education, which should clearly separate Medical Communications Agencies, the promotional agencies of industry, from the education providers of independent education. The lack of a clear definition has led to agents of pharmaceutical companies being allowed to control CME-CPD activities, at the expense of compliant education providers.

CONTACT Monica Ghidinelli monica.ghidinelli@aofoundation.org AO Foundation, AO Education Institute, Stettbachstrasse 6, Duebendorf 8600, Switzerland

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The Pharmaceutical Industry

We acknowledge that industry has a legitimate business role in promoting their products and services and in educating healthcare professionals in their disease areas of interest, which they do effectively and to a high standard. Industry also provides CME-CPD-compliant sources of financial support for third parties for education that is designed, developed and presented independently of pharmaceutical industry regulatory control [2]. This is overseen and enforced by the relevant national regulator whose Codes of Practice fall largely in line with the collaboratively developed EFPIA Code of Practice [3]. It is this type of provision of independent financial support to third parties that members of the Good CME Practice group, who do not engage in developing promotional materials, are able to access to provide independent accredited education to healthcare professionals.

We described in our previous letter to this journal in 2017 [4] how the pharmaceutical industry – represented by the international Pharmaceutical Alliance for CME (iPACME) and EFPIA – had presented at the 9th Annual European CME Forum new broadly agreed concepts for how pharma funds different types of promotion and education [5] which was subsequently published [2]. Several European members of iPACME were on the EFPIA Working Group that eventually codified these principles as a new Article 16 in the 2019 EFPIA Code of Practice [3], providing detailed Guidance [6] and a letter to this journal with further explanation for the CME-CPD community in Europe [7].

The EFPIA Code of Practice is essentially a template, and its enforcement comes as it is adopted on a country level by the national regulatory authorities. The regulator in the UK, the Prescription Medicines Code of Practice Authority (PMCPA), adopted only partially the new EFPIA Article 16 into the national codex, the Association of the British Pharmaceutical Industry (ABPI) Code of Practice [8]. This has led to a conflict of regulations as only a few of the Royal Colleges and Faculties, the accreditation bodies in the UK, require regulator-defined independence from industry-control in accredited CME-CPD (called CPD approval in the UK). This creates a risky situation as we explain in the following paragraph.

Current Challenges Impacting Independent CME-CPD in Europe

We would like to illustrate the challenges we face with two recent examples. The first is in the UK in 2022, where the PMCPA investigated a UK-accredited educational activity, funded by an international independent education grant. The supporting pharmaceutical company was found to have breached the ABPI Code of Practice by not controlling the content of the education being presented [9].

This case highlights that in UK there is no chance for provision of independent education as the PMCPA has not implemented the parts about independence from industry control. In addition, an education provider that receives international independent grant funding cannot simultaneously be compliant with the grant contractual agreement (based on EFPIA Article 16 requirements) and with the UK ABPI Code of Practice. This then means the international grant office of the funder falls foul of breaching the EFPIA Article 16, or equivalent, in another country!

This Catch-22 situation has not gone unnoticed by other pharmaceutical companies. Indeed, our group members experienced that since early 2023 several pharmaceutical companies have excluded the UK from international grant funding of CME-CPD activities, as well as received explicit instruction to exclude UK healthcare professionals from their internationally funded independent CME-CPD, whether or not it has been accredited.

The second challenge regards accreditation standards. We note that the new "EACCME 3.0" standards, launched by UEMS-EACCME on 16 May 2023 for implementation on 19 June 2023 [10], continues to use ambiguous definitions. The new standards do not differentiate between "medical communications agencies" where content is required to be reviewed and controlled by the industry supporter and education providers who work under arms-length grant agreements with no input from the supporter.

In the definition of unrestricted financial support: the term "support" implies no involvement of the funding company, however the continued use of the term "unrestricted" remains unhelpful as it is not recognised in any compliance, legal, tax or accounting sphere. While the sentiment indicates that the funding company is not allowed to be involved in any way, restrictions in themselves need to be imposed. The terms of the grant need to specify these, such as the amount of funding, the limitations of the use of the funding (e.g. geographical scope, disease area), what the funding cannot be used for (e.g. entertainment, delegate travel), and other important information that transparently defines the legitimate purpose of the funding. Care should also be taken when using the term "sponsorship" as this requires some kind of benefit to be

returned to the funding company. This is acceptable when the benefit is, for example, space for an exhibit, but funding the educational activity itself will mean a requirement for the funder to have a level of control of the educational content itself, which is inappropriate when funding CME-CPD.

Withdrawal from accrediting satellite symposia further diminishes CME in Europe. Previously, independent education providers were able to develop valuable education for physicians attending a congress under an independent grant; in the absence of such "accredited symposia" congress delegates will only have access to promotional satellite symposia. We feel that EACCME has missed a timely opportunity to have updated their standards to tighten definitions around the independence of CME-CPD, increase transparency, better differentiate independent education providers from medical communications agencies withing with industry, and to nurture an expanding European CME-CPD environment.

Conclusion

Members of the Good CME Practice group, a membership group of education providers in Europe, are in a privileged position to observe both subtle and seismic changes in the CME-CPD community. Members are uniquely positioned to be navigating national laws, European and US industry regulations and standards of all the major European, national and US accreditors. All full members of the group implement their activities according to our Four Core Principles of Appropriate Education, Balance, Transparency and Effectiveness [11].

We implore the European and national accreditors to acknowledge that independence from industry control is sacrosanct in accredited CME-CPD and is in the interests of their healthcare professionals so that the continuing education they receive is free from influence or control by industry. The work of the International Academy for CPD Accreditation (IACPDA) in recent years on standards in accreditation systems has led to some interesting definitions that we think would be suitable for implementation across Europe [12]. Even in several countries across Europe where it is acceptable for industry to control education, there needs to be a separate process where education that is supported by, but not controlled by, industry is accepted and recognised. This would then prevent industry from making it a contractual obligation to uninvite or block healthcare professionals from educational activities, in order to comply with their own regulatory obligations.

In the light of the recent developments, we would like to offer ourselves (gCMEp) to act as mediators, or as "informed outsiders" to help national and European accreditors to draw up standards that reflect the present regulatory and legal environment. It is critical that there are meaningful and enforceable standards, as well as practical guidance, to help CME-CPD in Europe become a valuable and practical tool to improve clinical practice, that leads to better patient care and outcomes, rather than being seen as a bureaucratic burden.

We will start by supporting the discussion of this topic during our planned sessions at the upcoming 16th Annual European CME Forum taking place in The Hague this November [13].

Disclosure statement

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The Good CME Practice group is a membership organisation for European CME providers; member organisations are listed at www.gCMEp.org.

ORCID

Monica Ghidinelli http://orcid.org/0000-0002-7378-6273
Eugene Pozniak http://orcid.org/0000-0002-9744-1317
Celeste Kolanko http://orcid.org/0000-0002-9249-3898
Sophie Wilson http://orcid.org/0009-0008-9457-9653

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