#### POSITION PAPER

\_\_\_\_\_

Taylor & Francis

OPEN ACCESS Check for updates

CME Forum

# Regulating for Bias in Medical Education – Reaction to the Pharmaceutical Industry Updated EFPIA Code of Practice

Marcin Rodzinka<sup>a</sup>, Annabel Seebohm<sup>b</sup>, Eugene Pozniak<sup>c</sup>, Lina Mosch<sup>d</sup>, Lara De Luca<sup>d</sup>, Jill McArdle<sup>e</sup>, Reinhard Griebenow<sup>f</sup> and Margarita Velcheva<sup>g</sup>

<sup>a</sup>Mental Health Europe, Brussels, Belgium; <sup>b</sup>Standing Committee of European Doctors, Brussels, Belgium; <sup>c</sup>European CME Forum, Manchester, UK; <sup>d</sup>European Medical Students' Association, Brussels, Belgium; <sup>e</sup>Global Health Advocates, Brussels, Belgium; <sup>f</sup>Continuing Medical Education – European Accreditators Registered Association, Cologne, Germany; <sup>g</sup>Good CME Practice Group, Manchester, UK

#### ABSTRACT

The European Federation of Pharmaceutical Industries and Associations (EFPIA) representing the pharmaceutical industry operating in Europe, introduced three codes of conduct between 2007 and 2013, which had a common goal of self-regulating interactions with healthcare professionals and patient organisations. This former set of rules was appreciated as a first self-regulatory step, although self-regulation itself is still considered by many stakeholders as insufficient to provide thorough transparency. EFPIA agreed to replace the separate codes with a new, consolidated EFPIA Code of Practice. The consolidated Code was broadened to include a new section on medical education that outlines the scope of member companies' engagement in "medical education activities?. This new section is controversial as it explicitly confirms that EFPIA members can be involved in medical education. In our view "independent Medical Education" per se prevents industry from "organising" events, i.e. industry must not influence content, presentation, choice of lecturers or publication of results. What is more, only events respecting this key principle (amongst others) can be recognised for purposes of continuing medical education/ continuing professional development (CME/CPD). A substantial portion of the medical education is currently funded by the pharmaceutical and medical device industries. This practice carries a significant risk to public and personal health, especially if it is not adequately safeguarded by a high standard of accreditation. We are most concerned by the fact that EFPIA, representing the pharmaceutical industry, is trying to broaden the approach to medical education, to include activities that are not independently evaluated as free from undue influence and conflicts of interest. We believe that in order to preserve scientific integrity and independence, pharmaceutical companies must not be granted the right to influence the content of medical education.

#### **ARTICLE HISTORY**

Received 15 October 2019 Accepted 15 October 2019

#### **KEYWORDS**

Medical education; transparency; conflict of interests; continuing medical education (CME); accreditation; independence; pharmaceutical industry

#### Background

The European Federation of Pharmaceutical Industries and Associations (EFPIA) representing the pharmaceutical industry operating in Europe, introduced three codes of conduct between 2007 and 2013, which had a common goal of self-regulating interactions with healthcare professionals and patient organisations. These codes covered topics such as promotion of prescription-only medicines and other relationships with healthcare professionals (HCPs), interactions with patients and healthcare organisations, and disclosure of selected information to the public.

This former set of rules was appreciated as a first self-regulatory step, although self-regulation itself is still considered by many stakeholders as insufficient to provide thorough transparency. On 27 June 2019, the General Assembly of EFPIA agreed to replace the separate codes with a new, consolidated EFPIA Code of Practice. This new Code features some new definitions (e.g. patient organisation representative) and aligns its provisions with the International Federation of Pharmaceutical Manufacturers & Associations Code of Practice.

The consolidated Code was broadened to include a new section on medical education that outlines the scope of member companies' engagement in "medical education activities". This new section is controversial as it explicitly confirms that EFPIA members can be involved in medical education. They can do so either by funding so-called "independent Medical Education", although a definition of what is meant by independent is lacking, or by organising and providing input in the content of "Medical Education activities". The differences

CONTACT Marcin Rodzinka 🔯 marcin.rodzinka@mhe-sme.org 🗊 Mental Health Europe, Brussels, Belgium

We represent seven organisations and are writing to highlight the shortcomings in the new EFPIA Code of Practice which allows the pharmaceutical industry to interfere with the content of medical education and to conceal promotional and informational activities under the guise of education.

© 2019 The Author(s). Published by Informa UK Limited, trading as Taylor & Francis Group.

This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial License (http://creativecommons.org/licenses/by-nc/4.0/), which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

between these two types of education are not described, making the use of such terms open to interpretation and confusion, to both physicians and providers. Moreover, while the Code says that "content (provided by industry) must be fair, balanced and objective, and designed to allow the expression of diverse theories and recognised opinions", it is not stated who is to be judge of such fairness and objectiveness, nor is there any reference to formal accreditation.

In our view "independent Medical Education" per se prevents industry from "organising" events, i.e. industry must not influence content, presentation, choice of lecturers or publication of results. What is more, only events respecting this key principle (amongst others) can be recognised for purposes of continuing medical education/continuing professional development (CME/CPD).

## Influence of Industry Funding on Medical Practice

Safety and quality of healthcare provided to users and patients depend heavily on workforces' competences and their knowledge. Doctors and other HCPs are asked to fulfil a long list of requirements in order to obtain the right to practice. As a follow-up to their initial education, they are also obliged to stay up to date with recent scientific developments and must constantly strive to improve their practical skills.

A substantial portion of medical education is currently funded by the pharmaceutical and medical device industries. This practice carries a significant risk to public and personal health, especially if it is not adequately safeguarded by a high standard of accreditation [1].

The pharmaceutical and device industries can influence educational events by favouring new therapeutic products manufactured by them or by playing down alternatives to medication such as diet, physical activity and other non-pharmacological approaches. This can be achieved, for instance, through narrowing the range of topics covered in such educational programmes. Moreover, evidence and content can be presented in a biased way that benefits the commercial interests of the financing bodies.

It is known that industrial interferences in medical education may unduly influence professional judgements. Physicians who attend company-sponsored educational events tend to have more positive attitudes towards, and higher inclination to prescribe, funders' branded drugs, even if others may be more effective, safer, and less costly. In general, HCPs receiving benefits such as access to medical education from pharmaceutical companies are shown to have a higher frequency of making decisions in line with the interest of these companies [2]. All this can jeopardise users' and patients' safety.

### **Critical Aspects**

We are most concerned by the fact that EFPIA, representing the pharmaceutical industry, is trying to broaden the approach to medical education, to include activities that are not independently evaluated as free from undue influence and conflicts of interest. Given the available scientific evidence, medical education cannot encompass activities exclusively financed and organised by the industry, as this has been proven to be biased and not characterised by a comprehensive approach to education and professional development.

We recognise that the industry has the right to support its own commercial interests with information on products or on specific diseases. Yet, it is imperative that CME remains independent.

We believe that in order to preserve scientific integrity and independence, pharmaceutical companies must not be granted the right to influence the content of medical education.

Our position is based on the expectation that those who have commercial interests in the field of healthcare should have not any or restricted and scrutinised influence over the way that medical knowledge is transferred. This is to prevent any distortions of evidence and their subsequent negative impact on users, patients and health systems. We support the statement made by the Standing Committee of European Doctors in its guidelines on the transparency of relationships between physicians and the healthcare industry. The content and material of educational activities and events should be designed by independent organisers and may not be influenced by sponsoring companies. The independence of medical education is an essential primary interest in healthcare that should be protected against any secondary interest [3].

Continuing medical education is an ethical obligation and an essential element of up to date and innovative medical practice. Only fully independent medical education can contribute to improving patient outcomes and quality of care [4].

### **Disclosure statement**

No potential conflict of interest was reported by the authors.

#### References

- [1] Schofferman J. Industry-funded continuing medical education: the potential for bias. Pain Med. 2015;16(7):1252–1253.
- [2] Spurling GK, Mansfield PR, Montgomery DB, et al. Information from pharmaceutical companies and the

quality, quantity, and cost of physicians' prescribing: a systematic review. PLoS Med. 2010;7:e1000 352.

- [3] Mosch LK, Balciunas J, de Jong R, et al., Conflicts of Interest in Medical Education Settings, European Medical Students' Association, 2019
- [4] Allen T, Donde T, Hofstädter-Thalmann E, et al. Framework for industry engagement and quality principles for industry-provided medical education in Europe. J Eur CME. 2017;6(1):1348876.