

Continuing medical education

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Preamble

The purpose of this document is to provide additional interpretation and further guidance toward the relevant provisions of the Code of Practice. This Note for Guidance is not binding by itself. It must be read with the spirit of the Code in mind and always in accordance with applicable laws and regulations and other applicable industry codes. IFPMA member companies and member associations are encouraged to take into account the considerations given in this Note for Guidance when implementing the IFPMA Code of Practice in their daily practice. The overall intention of this Note for Guidance is that the cooperation between companies, healthcare professionals (HCPs), and other stakeholders is always based on high ethical standards and clearly aims to benefit patients.

Terminology

Terminology varies across regions and countries. It may include active provision of continuing medical education, as referred to in Section 10 of the IFPMA Code, with or without formal accreditation. Given the complicated language, we refer to this in this document as Medical Education, or ME (also known as Lifelong Learning in Medicine (LLLM)). It includes the provision of product-specific training or medical-disease-related education, the support or provision of Continued Professional Development initiatives (CPD) or Quality Improvement initiatives (QI) relevant to ME, or the financial support of accredited programs that are typically described as Independent Medical Education (IME).

Continued Professional Development (CPD)

CPD is a continuing learning process, outside formal undergraduate and postgraduate training, which enables doctors to maintain and improve their performance across all areas of their practice through the development of knowledge, skills, attitudes, and behaviours. It covers all learning activities, both formal and informal, by which doctors keep up to date.

Quality Improvement (QI) relevant to ME

QI relevant to ME consists of systematic and continuous actions that lead to measurable improvement in healthcare services and the health status of targeted patient groups.

Independent medical education (IME/CME), which could be funded by industry but its

scientific program and content are always decided independently from the industry. The audience is identified and invited by the organizer and not the pharmaceutical company. The role of the pharmaceutical company must be declared as required by Section 2.2 of the IFPMA Code.

In order to clarify and to avoid confusion, we use the term Continuing Medical Education (CME) to refer to formal and accredited structures, and ME when referring to the entire body of practices used to educate HCPs. This includes CME, CPD, and QI.

Introduction

In many countries, a variety of ME offerings are provided through several mechanisms, many of which recognize the legitimate and important role for the pharmaceutical industry in supporting ME to improve healthcare professionals' knowledge, skills, competence, or performance. However, in some countries, no such structured mechanisms to ensure healthcare professionals remain up to date have been implemented. In these countries, the pharmaceutical industry is committed to help support healthcare professionals' access to quality ME, which may include providing ME.

This Note for Guidance is not intended to supplant established mechanisms to regulate or provide guidance on accredited CME activities. This Note for Guidance provides a framework to support quality ME in those countries where there are no structured mechanisms, other than the pharmaceutical industry's codes of practice.

The quality and integrity of ME is crucial as it is intended to help HCPs expand their knowledge, skills, competence, or professional performance with the ultimate goal of improving patient outcomes. It is helpful to identify and prioritize the key patient and HCP educational needs to discuss these and other priorities with relevant local stakeholders. It is important to assess infrastructure limitations when designing and delivering ME in under-served, remote regions.

The purpose of this document is to provide guidance to pharmaceutical companies to ensure that their involvement in the provision of ME meets high standards. The guidance might also be helpful to medical device/technology companies. Pharmaceutical companies must ensure that their own internal procedures operate in compliance with local codes and laws.

In addition to ensuring quality ME activities comply with relevant codes and laws, pharmaceutical companies should consider:

1. Partnering, where appropriate, with government and academic institutions, professional associations, hospitals, and/or third-party providers
2. Engaging with healthcare networks to provide content, designed and tailored to regional and country-specific needs

3. Under-served groups of healthcare providers (such as those in remote areas with poor internet connectivity, those who do not currently participate, and those with affordability issues) and aligning with core public health needs.

Key stakeholders in ME

Key stakeholders accountable for providing or supporting the provision of ME and LLLM include government and policy makers, academic institutions, professional associations, scientific organizations, logistics agencies, hospitals, third-party medical education providers, and pharmaceutical, biotechnology, and medical device/technology companies.

It is important to identify and know the role of key stakeholder(s) responsible for addressing regional or country-specific medical education needs as they may vary considerably. When working with providers, pharmaceutical companies must ensure that they take time to assess potential partners.

ME approaches

ME must keep pace with changes in medicine and ensure that HCPs stay up to date and develop their skills to ensure high quality patient care. Pharmaceutical companies have a significant role to play in the provision of ME. Their involvement with ME must meet the relevant requirements of local codes and laws, and must never have the primary aim of increasing prescriptions or sales.

Pharmaceutical companies may assist with the provision of ME in a variety of ways. It may be CME-accredited by one or more independent bodies, depending on the framework in a particular country.

1. **(IME/CME)**, which could be funded by industry, but its scientific program, speakers, and content are always decided independently from the industry. The audience is identified and invited by the organizer and not the pharmaceutical company. The role of the pharmaceutical company must be declared as required by Section 2.2 of the IFPMA Code.
2. **ME through collaboration / partnership**, which is provided by one or more pharmaceutical company and other key stakeholders, working together toward mutually established ME goals in a collaborative setting. Such arrangements should be formalized by a written agreement, and effective collaborations and partnerships should have the following characteristics:
 - Clear intent and objectives of the ME program, defined at the beginning and agreed by the parties
 - Clearly defined areas of responsibility and deliverables for each party
 - Transparency and disclosure of financial support, depending on the framework in a particular country

- 3. Pharmaceutical-industry-led ME activities**, which may address specific disease-related topics and/or product-specific topics. Although these activities are initiated and provided by the pharmaceutical industry, disease-related educational activities might also involve scientific organizations or professional associations.

Quality and ethics in ME

Both quality and an ethical approach to ME must be the key priorities for all CME providers.¹

ME providers should consider the following criteria as a minimum:

- Program should have clear educational objectives to support high-quality patient care
- Content should be balanced, fair, ethical, and up to date
- Roles and responsibilities of the parties should be agreed, documented, and clearly communicated
- Ongoing evaluation should be an integral component of the program
- The ability of the intended audience to access programs
- Funding by pharmaceutical companies should be reasonable and appropriate (fair-market value) and disclosed according to transparency principles and requirements.

Conclusion

The global pharmaceutical industry is committed to make an impactful contribution to ME. Key stakeholders should strive to identify areas in collaboration to address critical needs and/or learning gaps through the implementation of high-quality ME programs to support patient care and to ensure a credible, scientifically balanced, and practical approach that will bring benefits to patients and improve overall healthcare outcomes.

¹ Allen T, et al. Framework for industry engagement and quality principles for industry-provided medical education in Europe. Available from: <https://doi.org/10.1080/21614083.2017.1348876>. Accessed September 2017.