European Federation of Pharmaceutical Industries and Associations

EFPIA Guideline on a Quality Framework Principles in Lifelong Learning in Healthcare

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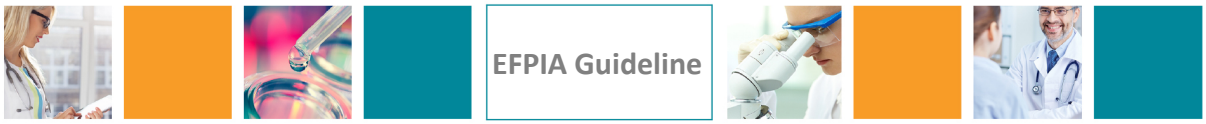

EXECUTIVE SUMMARY

Lifelong Learning is defined by the European Commission as 'all learning activity undertaken throughout life, with the aim of improving knowledge, skills, competences within a personal, civic, social and/or employment related perspective[1]'. The pharmaceutical industry has a longstanding commitment to engaging and innovating in Lifelong Learning in Healthcare (LLH). This non-binding guideline for EFPIA Members Companies provides definition and standards for quality, transparency and ethics in medical learning. Adhering to the principles in this guideline, will assist the pharmaceutical industry to ensure a disciplined approach to the funding and organisation of LLH and its continued contribution to improved patient outcomes. Adherence to laws and regulations, and organizing up-to-date, fair and balanced learning programmes remains essential to the development of quality educational programmes. By implementing and/or maintaining this approach to LLH, the pharmaceutical industry agrees to formally incorporate educational principles of LLH, provide transparency and facilitate working effectively with other stakeholders in healthcare.

[1] Communication from the Commission COM (2001) 678 – Making a European Area of Lifelong Learning a Reality: https://www.europarl.europa.eu/meetdocs/committees/cult/20020122/com(2001)678_en.pdf

Preamble

The purpose of this document is to provide a guideline for the implementation of EFPIA Code Article 16. The guideline must be read with the requirements and spirit of the Code in mind and in accordance with applicable laws and regulations, in particular, the EU Directive 2001/83/EC Titles VIII and VIIIa on information and advertising.
The intention of this guideline is to ensure that LLH by the pharmaceutical industry adheres to high ethical standards and robust educational principles with the ultimate common goal to benefit patients. LLH must not constitute promotion.

High scientific standards and the process of quality assurance for medical learning programmes are required to maximize transparency, ensure quality, fair and balanced content, and mitigate bias. The pharmaceutical industry strives to use educational principles which are based on, learner-centric engagement to advance the value and impact of learning.

The Value of the Pharmaceutical Industry in LLH

The pharmaceutical industry has a legitimate role among other stakeholders in providing evidence to ensure innovations are used safely and in the appropriate patient populations.

To keep up with the speed and breadth of scientific and medical progress, different LLH providers are needed for rapid diffusion of new evidence and innovations in healthcare. Given that the pharmaceutical industry must ensure its medicines are used safely and in the right populations, it provides important high quality and a complementary channel for LLH.

To facilitate a robust and practical learning experience with a fair and balanced presentation of evidence, the pharmaceutical industry often partners with leading and recognised experts.

The pharmaceutical industry is in constant dialogue with healthcare professionals at the global, regional and local levels and may be in a position to identify and address learning needs that may not be covered by other providers of LLH.

With its large geographic footprint, the pharmaceutical industry can provide opportunities for education to HCPs in countries with limited access to LLH offerings.

With innovation in therapeutic areas, the pharmaceutical industry is frequently at the forefront of the provision of LLH to assist and accelerate the translation of clinical research and other advancements into clinical practice.

Introduction

Multiple terms are used to describe learning and Continuous Professional Development (CPD). These vary across regions and countries and may or may not be associated with formal accreditation. In the EFPIA Code Article 16 as well as in this document the term Lifelong Learning in Healthcare (LLH) is used to describe non promotional educational activities led and/or funded by the pharmaceutical industry and that fulfil unmet educational needs in healthcare.

LLH must not be to promote company products, devices or healthcare solutions, but to translate evidence relevant for enhancing patient care into respective learning interventions in disease areas. Company-driven, product only specific educational activities which promote medicinal products are out of scope for this document. Such activities must comply with laws and regulations for the promotion of medicines.

The following types of educational activities are covered by this guideline and have common objectives, but differ as to the level of pharmaceutical industry involvement, ownership and funding:

1. Independent Medical Education (IME), with or without Continuous Medical Education (CME) or Continuous Professional Development (CPD) accreditation. IME is conducted by an independent organisation without industry involvement or influence and can be funded by the pharmaceutical industry.

2. LLH programmes developed through collaboration or partnership of one or more pharmaceutical company(ies) with professional societies, healthcare organizations, education providers, or other key stakeholders. The collaboration/partnership includes a commitment to a definition of mutual relationships and goals; a jointly developed structure and shared responsibility; mutual authority and accountability for success.

3. Pharmaceutical industry led LLH activities, which may address human health, and diseases - specific learning needs. These activities are organized by individual pharmaceutical companies and may involve scientific committees, and/or independent scientific and professional organisations. Ownership, accountability and funding for these programmes remains that of the pharmaceutical company.

Whatever the type of LLH, the pharmaceutical industry is committed to delivering and supporting high-quality learning. The pharmaceutical industry expects other stakeholders, such as IME providers, scientific committees, scientific organizations or professional associations to adhere to the following principles when receiving pharmaceutical industry support/funding for LLH.

Quality Framework

This document describes the following 3 elements:

1. Ethical, transparent and responsible engagement;
2. Quality content: programmes and activities must not be promotional, either in content or intent; and
3. Robust processes: educational needs assessment, learning design and outcomes measurement.

Ethical, transparent and responsible engagement is mandatory for any LLH activity. Quality content and robust processes are strongly recommended to meet the highest quality learning standards and educational impact.

1. Mandatory requirements: Ethical, transparent, and responsible engagement

Ethical, transparent and responsible engagement is the overarching and basic principle of the quality framework and is mandatory. It is supported by robust educational processes and quality content. It is the responsibility of the funding pharmaceutical company to ensure the scientific integrity of LLH activity.

The purpose of ethical, transparent and responsible engagement is to address the following major considerations:

- **Funding**: Transparency regarding the reporting of funding and other value provided to those delivering or receiving the education as per EFPIA Code Chapter 2 and 5
- **Disclosure**: Disclosure of interests and potential conflicts of interest for any activity type of LLH by all party(ies) involved
- **Intent:** Transparency regarding intent, involvement, roles and responsibilities and nature of potential collaboration with external stakeholders (clinicians, medical associations/organizations)
- **Data privacy:** respect regulations (such as per GDPR)
- **Compliance** with pharmaceutical industry codes of practice [such as IFPMA, EFPIA], EU regulations and local applicable laws and regulations

2. Recommended practices

2.1 Quality content

The objective of LLH is to increase the scientific knowledge and competence of HCPs to enhance medical practice and improve the overall patient and healthcare outcomes. Quality content is the foundation of LLH.

To ensure high quality content is provided by pharmaceutical industry led and/or funded LLH activities, the programmes must not be promotional, either in content or intent. They must not include product branding (trade name, logo, brand colours etc.), nor product claims.

It is recommended that a scientific committee formed of experts in the specific disease areas is responsible for developing the agenda/programme, selecting the faculty and guaranteeing the scientific integrity of the programme. With the exception of IME, members of pharmaceutical industry scientific/medical functions and therapeutic area specialists can be members of scientific committees.

Companies should consider the following principles in order to ensure high quality content for LLH programmes:

- Needs-based: needs may be identified through scientific literature review, by a scientific committee and/or a dedicated educational needs assessment - see Section 3.1
- Up to date, factual and of high scientific standard capable of substantiation: use of the most appropriate, current and evidence-based content relevant to current clinical practice and standards
- Balanced and objective: provision of scientifically balanced perspectives on the subject matter with involvement of independent scientific input when appropriate and allowing time for scientific peer to peer exchange
- Incorporates multiple sources of scientific data
- Referenced: all content should be referenced so learners can assess the level of statistical and clinical relevance of the content

Different learning styles, the cultural differences of the audience and modes of delivery should be considered to best meet the learning objectives. All components of the programme, regardless of method, design or channel (digital, visual and practical) must give a clear, fair and balanced view of the information/data they aim to convey and allow the expression of diverse theories and recognised opinions.

2.2 Robust processes

To ensure high educational quality; a robust and standardized process is strongly recommended, including:

- Educational needs assessment
- Learning design
- Outcomes assessment

Each pharmaceutical company will individualise their own educational processes. Examples below are intended to assist companies in the design of their processes

2.2.1. Educational needs assessment

A disciplined and accurate assessment of programme participants´ learning needs is a recommended initial step in planning educational activities and should ensure clarity on the selection criteria. Selection of delegates should be based on educational needs.

Needs can be classified as:

- Perceived needs; expressed and perceived by learners– e.g. a survey among HCPs attending a specific LLH activity
- Expressed needs; expressed in action – e.g. a clinical centre's need to understand new guidelines in clinical practice
- Normative needs; stated by experts

- Comparative needs; expressed in group comparison for instance between clinical institutions and their clinical practice.

An educational needs assessment should include input from multiple stakeholders in healthcare. Methods for assessing learner´s needs can include reviewing literature, qualitative exploratory research, surveys, input from experts and other stakeholders in healthcare, advisory boards and multiple other data collection methods.

2.2.2. Learning design

The current healthcare ecosystem is undergoing a major transformation. This is driven by a more patient centric approach towards healthcare and vast improvements in technology. This transformation requires all stakeholders in the healthcare ecosystem to collaborate for LLH processes to meet high educational standards.

A quality assurance framework[2] may include a standardized process for learning design and should be part of a developed higher-level strategy that aims at increasing the scientific knowledge and competence of HCPs to enhance medical practice and improve patient and healthcare outcomes.

Such processes could include an outcomes-based planning approach and should communicate what LLH should achieve. The following steps may be used in education:

1. Identify the intended outcomes based on educational needs (see needs assessment)
2. Agree on acceptable evidence e.g. discuss programme and faculty with scientific committee based on identified learning outcomes
3. Plan the learning experience

2.2.3. Outcomes measurement

To ensure continuous improvement in LLH, different approaches for measurement should be used and outcomes used to improve future programmes. Measurements may apply to different learning or instructional design and delivery channels. Although objective measures are preferred, subjective measures are used where the opinion of learners is sought, (e.g. ‘satisfaction’ or ‘relevance’).

[2]Anderson et al, Moore et all, Michie et all

Recommended bibliography

EFPIA Code of Practice: https://www.efpia.eu/media/602690/310521-efpia-code.pdf

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