

Global Compliance Codes Update

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Codes consolidation process



- * In April 2018, Board mandate to consolidate the 3 EFPIA Codes into one simplified version
- * Consolidation made on a collaborative, transparent and consensual process internally and externally
 - * Draft sent for information before the Board approval to our main stakeholders: CPME, BioMed Alliance, Patient Organisations and IPCAA
- * This consolidation exercise has demonstrated that it is impossible to merge 3 Codes without any changes
 - * These changes have been limited to what is absolutely necessary and well established in the current practices

Stakeholders feedback

Objectives: information before finalization and give the opportunity to share any concerns before the Board approval



* Feedback received from: **BioMed Alliance, European Men Health Forum, Mental Health Europe, IPCAA**

* **Overall positive**

- * MHE welcomes some changes (among others, the inclusion of PO's representatives, the alignment on disclosure reporting period and the recommendation to create disclosure gateways).
- * Nevertheless, the association expresses its regret to see that Patients are outside of the disclosure's scope. Additionally, MHE believes that pharmaceutical companies should not have input in the content of medical education because it creates a direct conflict of interest and a risk of bias in education provided to HCPs.

Changes introduced to simplify the concepts

Objective: better concept alignment and promote the common understanding of the Code by stakeholders and general public aiming to improve adherence

- * Introduction of common definitions
 - * HCP definition extended to any public officials
- * Integration of the EFPIA Ethical Principles in the introduction
- * Definition of a new structure to cover all type of interactions and bring clarity on the interactions:
 - * Common principles for interactions with HCPs/HCOs/POs
 - * Specific requirements for interactions with HCPs and HCOs or POs
- * All the relevant existing guidance have been integrated into the Annexes
- * Removal of the repetitive provisions



Changes introduced to clarify the content

During the revision of the 3 Codes, some principles or requirements have been changed after a deep analysis of the consequences

- * Extension of the gift prohibition to POs and their representatives
- * Extension to HCOs of the principles applicable to company funding
- * Distinction of sponsorship provided to HCOs and contribution to costs of events provided to HCPs
- * Introduction of an article related to Medical Education
- * Prohibition of product branded for IEM and IMU (IFPMA wording)
- * In the disclosure requirements, removal of the references to the consent



Next steps

- * Submission to the General Assembly on 27 June 2019
- * Member Associations' transposition in one year delay (i.e. June 2020)
 - * Implementation at the latest in **January 2021**

- * Development of a communication plan

- * Updating the additional documents:
 - * FAQs
 - * Internet guidelines
 - * PO Disclosure template



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