

SIGNIFICANT CHANGES INTRODUCED BY KEFPA CODE ADOPTED ON 15.12.22

General changes

- * 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 template for PO written agreement
 - * EFPIA's objective to draft a new template in collaboration with POs – we will use it as the basis for ours as well, in due course
- * Removal of the guidelines for Internet websites
 - * Objective to update them as soon as possible once we have guidance from EFPIA

Specific changes

Provision	Old Code(s)	New Code
Preamble	Separate documents for Code of Conduct, Disclosure Code and Code of Practice on Relationships between the Pharmaceutical Industry and POs ("Patient Code")	One document
	No explicit reference to digital communications and interactions	Explicitly states that this Code applies to all types of communication and interaction (traditional and digital)
	No integration of EFPIA's ethical principles	EFPIA's ethical principles have been explicitly included
	No introduction in Patient Code	Specific section in introduction to refer to importance of patients and POs
Definitions	No definition for contribution to costs related to events	Definition has been introduced in "Definitions" section
	No definition for donations and grants	
	No definition for government official	
	No definition for PO representative	
	Satellite symposia were not included in the definition	

HCP	Definitions were not aligned	Definition has now been aligned in “Definitions” section and includes GOs
Events	Article 19 split it into (a) Congresses of scientific content, (b) Events aimed at providing medical information and (c) Events for the promotion of sales.	All these have been amalgamated into one definition for “Events” in “Definitions” section
	No provision for accompanying person	Hospitality may only be extended to persons who qualify as participants in their own right. In exceptional cases of established health needs (e.g. disability or injury), the travel, meals, accommodation and genuine registration fee costs of an accompanying person can be reimbursed within the same parameters. (section 10.06)
Thresholds	EUR 70 per person per meal (excluding taxes and tips)	EUR 75 per person per meal (excluding taxes and tips) (section 10.03)
	No accommodation threshold for events held outside Cyprus	EUR 400 per night (section 10.05)
Gifts	Provisions were not aligned	Gifts and promotional aids are explicitly prohibited (section 11)
Donations and grants to HCOs and POs	inconsistent	Provision now explicitly also applies to POs (article 12)
Contribution to costs related to events and sponsorship	Concepts were not clearly separate, e.g. section 24.3.01.1.b “Contribution to costs related to Events. Contribution to costs related to Events, including sponsorship of HCPs directly or through HCOs to attend Events, such as: i. Registration fees; ii. Sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event; and iii. Travel and accommodation (to the extent governed by Article 19.).”	Contribution to Costs Related to Events (<i>support providing or covering the costs of meals, travel, accommodation and/or registration fees to support the attendance of an individual HCP or PO Representative to an Event organised or created by a KEFEA member and/or a Third Party</i>) and Sponsorship (<i>support provided by or on behalf of a KEFEA member, when permitted by law, as a contribution to support an activity (including an Event) performed, organised or created by a HCO, a PO or a Third Party</i>) are two separate concepts in definitions
		This section has now been extended to POs
Logos	Need to obtain permission from PO for use of logo	Obligation now also applies to HCOs (section 13.02)
Acknowledgment of Sponsorship	Need to ensure that Sponsorship to POs is clearly acknowledged and apparent from outset	Obligation now also applies to HCOs (section 13.03)

Member Company Funding	Principle that no member company can require to be the sole funder or sponsor of a PO's activity	Principle that no member company can require to be the sole funder or sponsor of an activity now also applies to HCOs (section 14)
Contracted services	No specific provisions re: remuneration or "minimal" apart from HCP remuneration	<p>(section 15) Compensation for <u>HCPs based in Cyprus</u> remains at threshold of not more than €170 per hour and for HCPs based outside Cyprus must be calculated with the threshold in the country of practice of the HCP;</p> <p>Compensation for <u>POs based in Cyprus</u> must be calculated with a threshold of not more than €100 per hour and for POs based outside Cyprus must be calculated with the threshold in the country of practice of the PO. Contractual arrangements need to be made with the PO itself, and payment effected only to POs – not to individuals.</p> <p>In the event that such an HCP or PO's representative is a Cyprus Government Official, care must be taken by KEFEA members to ensure that these approvals have been procured.</p> <p>"<u>Minimal</u>" remuneration, for the purposes of limited market research (section 15.04), means that there is an absolute cap of 3 hours' remuneration</p>
Medical Education/Lifelong Learning in Healthcare	No section on education/LLH	New section (section 16) – complemented by guidelines in Annex F
Informational or educational materials and items of medical utility	Branding guidelines were not completely clear	Branding guidelines are now clearer - Informational or Educational Materials and Items of Medical Utility <u>can include the Member Company name, but must not be product branded</u> , unless the Medicinal Product's name is essential for the correct use of the material or item by the patient (article 17)
Non-interventional studies	No section on NIS	New section (article 18) – see also Annex B (KEFEA Guidance on Disclosure of Non-Interventional Studies)

Scientific service	Brief reference in Article 12 of Code of Conduct	<p>Has been beefed up (section 20.01) and clarifies that the scientific service must include a suitably trained person with a healthcare scientific background who will be responsible for approving any promotional material before release. Such suitable training must be documented and kept up to date by the KEFEA member.</p> <p>Each KEFEA member must also appoint at least one senior employee who must be responsible for supervising the KEFEA member and its subsidiaries to ensure that the standards of the KEFEA Code are met.</p>
Disclosure of ToVs to HCPs, HCOs and POs	Mostly used consent as basis for disclosure	Section 22.01 and section 23.01 makes reference to the fact that consent is not the only legal basis for disclosure (might be legitimate interest grounds, legal duty, etc)
		Introduction of a common section for disclosure to HCPs, HCOs and POs (article 22)
	Disclosures shall be made in Greek or English	If in Greek, KEFEA members are encouraged to make disclosures additionally in English
		Annex B provides guidance on disclosure of NIS, of indirect ToVs through third parties and, of ToVs through PCOs
		Annex E provides optional but recommended template for PO Disclosures
Methodology for preparing disclosures and identifying support and services provided	Obligation for methodology was only to HCPs/HCOs	Obligation now also applies to PO disclosure (article 24)
Enforcement of Code	Only had 5-member Disciplinary Committee – procedures were not clear	Now have clear provisions + Appeals Board (Annex C)
	No section on awareness and education of members	Members are encouraged to share their respective interpretations of the KEFEA Code through the regular meetings organised by Compliance Committee.