Irish Pharmaceutical Healthcare Association

Main changes to Version 8.5 of the IPHA Code of Practice for the Pharmaceutical Industry 14 Mar 2025

The new IPHA Code of Practice for the Pharmaceutical Industry (V8.6) becomes effective on 01.06.25. The text below details the main differences between V8.5 and V8.6.

1.	Clause 1 (scope and definition of terms): definitions for the following have been added as per EFPIA requirements: Appropriate, Contribution to Costs Related to Events, Donations and grants, Gifts, Events, Extravagant, Inexpensive, Location, Minimal, Patient Organisation, Patient Organisation Representative, Personal Health Data, Reasonable, Renowned, Significant, Sponsorship and Trade Catalogues.
2.	Clause 7.1 (textual and audio-visual promotional material): this duplicative and unnecessary clause which states that '*All promotional material issued by a marketing authorisation holder or with his authority, must be consistent with the requirements of this Code'* has been deleted since the content is already stated in other areas of the Code.
3.	Clause 7.2 (textual and audio-visual promotional material): Due to the deletion of a clause the wording that was Clause 7.2 in the previous version is now Clause 7.1 in version 8.6. Furthermore, a new Clause 7.2 has been added. The amended section of Clause 7.1 and the new Clause 7.2 read as follows (new text in green): 7.1) Where the purpose of promotional material is to provide persons qualified to prescribe or supply a medicine in Ireland with sufficient information upon which to reach a decision for prescribing or for use, then the following minimum information, which must be compatible with the SmPC, must be given clearly and legibly and (except in the specific circumstances advised in Annex IV of the Code) must be an integral part of the advertisement (see also Clause 2.3(iv) in Annex IV in relation to the execution of this requirement for digital banner advertisements)… 7.2) A QR Code that links to directly to the required information outlined above may also be added to printed promotional advertisements, but it may not be a substitute for the aforementioned required information. Thus, if a QR Code is used in this circumstance it must be provided in addition to the printed version of the aforementioned required information. However, for full advertisements in the form of banner stands, or other stands, only, the aforementioned required information may be substituted by, 1) a prominent statement such as '*prescribing information is available at the adjacent company table'* if the aforementioned required information is provided at an adjacent company table, and/or 2) a QR code, if it links directly to the aforementioned required information.
4.	Clause 7.3(i): the HPRA now permits all three to be part of the advertisement and the relevant clause in the IPHA Code has been updated to reflect this as follows: The name of the medicine, and/ or the international non-proprietary name, where such exists, and/ or the trademark;
5.	Clause 7.12 (textual and audio-visual promotional material) has been deleted (the wording that was Clause 7.13 in the previous version is now Clause 7.12 in version 8.6): ~~*Audio-visual material must be accompanied by all appropriate printed material so that all relevant requirements of the Code are complied with*~~. -

6.	Clause 9 (References To Reimbursement Schemes: this section has been retitled, two clauses have been removed and the existing text has been replaced with renumbered clauses as follows, to provide members with greater clarity and flexibility: *For the purpose of informed decision making, companies may communicate the specific reimbursement status of a medicine subject to the following:* *9.1 The size and emphasis of the reimbursement statement must be proportionate to the rest of the information in the communication.* *9.2 The phrase "freely prescribable" or similar phrases that suggest a lack of restriction or restraint due to the cost of a medicine, or the source of its funding, must not be used.* *9.3 Reproductions of official documents, such as prescription forms, must not be used for promotional purposes without the agreement of the appropriate State Organisation.*
7.	Clause 12.10 (Company Employees (Direct and Contracted) has been replaced with the following: *12.10 Companies are responsible for the activities of all their employees (direct and contracted) and must ensure that employees who are involved in any activities covered by the Code are trained in, and compliant with, the requirements of the current version of the Code.* *Companies have an obligation to ensure that:* *a) third parties working for, or on, their behalf, (e.g. advertising companies, business consultants, market research companies etc) commissioned to engage in relevant activities covered by the Code and* *b) those that companies work in partnership with (such as joint ventures and licensees)* *are conversant, and compliant, with the current version of the Code, as applicable to the activities they are performing or in which they are partnering.*
8.	Clause 14.1 (Gifts): this has been amended to align with EFPIA requirements, and the prohibition of the provision of promotional aids, which has been in place for some time, is now explicitly stated in a new Clause 14.2. Clause 14.1 No gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to persons qualified to prescribe or supply by a company in relation to the promotion and /or marketing of prescription medicines. Providing or offering cash, cash equivalents or personal services is also prohibited. This does not preclude any regulations for the time being in force relating to prices, margins and discounts. Clause 14.2 Providing or offering a promotional aid to persons qualified to prescribe or supply, HCOs or Patient Organisations and their representatives in relation to the promotion of medicines, is prohibited
9.	Clause 15.1(viii) (Grants, healthcare support services and other forms of support): the following statement has been added as a second paragraph to Clause 15.1(viii) to streamline requirements. For ToVs that occur after 01.06.25, the company must ensure notification to senior management (of the HCO named in the ToV) of the ToV that will appear on the IPHA ToV website. Also, Clause 15.1(ix) which states the following, has been deleted ~~*Companies must obtain written confirmation of the authorised account for ToV payments from the CEO, Finance Director or other comparable role of the HCO.*~~
10.	Clause 16.3(i) (Threshold for meals and drinks): the threshold has been increased by €10 to €90, based on the consumer price index and the current rate of inflation. Also, the following text has been added to meet the EFPIA requirement that National Associations provide guidance on how to deal with non-EFPIA countries. For non-EFPIA countries the host country principle is permissible and where one does not exist the home country threshold applies. For events held in EFPIA countries, the monetary threshold for a meal is the threshold of the country in which the event is taking place.

11.	Clause 16.7 (Hospitality, Sponsorship and Meetings): the following sentence has been added: Each company that invites a HCP to attend a company organized meeting must clearly disclose, in the invitation, if the meeting is promotional.
12.	Clause 16.8 (vi) (International Conferences): the following Clause 16.8 (vi) regarding EFPIA's e4ethics has been added: If a company participates in, collaborates with, or sponsors a European third-party organised event with more than 500 HCPs attending that have come from at least five different EFPIA countries, the event must be qualified under EFPIA e4ethics platform.
13.	Clause 16.9 (meetings convened by HCPs): the categorisation of meetings into 'smaller' and 'larger' meetings has been removed. The existing requirements pertain to all meetings convened by HCPs.
14.	Clauses 17.3, 17.5 (Medical Education): minor clarification and administrative changes.
15.	Annex I (Administration of the Code and Complaints procedure): the number of non-IPHA signatories that may be included in the Code Panel has been increased from one to four. Clause 3.1 now reads 'A maximum of four persons drawn from non-IPHA signatories'.
16.	Annex I Clause 4.5 (withdrawal of complaints): the following is now included after the first paragraph of that clause: The Complainant may only withdraw their complaint if they have identified a valid reason to believe that the Respondent did not breach the Code and such justification has been provided, in writing, to the Code Council Chair.
17.	Annex 1 Clause 8 (Sanctions): the clause has been slightly reworded and the new wording is in green below: Sanctions must be proportionate to the nature of the infringement, have a deterrent effect and take account of repeated offences of a similar nature or patterns of different offences. Where the Code Council, having considered a complaint or referral, has found that the Code has been breached it shall, without prejudice to the right of any affected party to have the matter resolved through the judicial process, have the authority to: (i) Require the company concerned to cease the practice found to be in breach of the Code. Take all necessary steps to avoid a similar breach in the future and provide proof of same to the Code Council within a defined period as decided by the Chair of the Code Council; (ii) Order the recovery of material found to have been in breach of the Code; (iii) Order the correction of inaccurate information by way of direct contact with relevant healthcare professionals or by publication, in the medical and/ or pharmaceutical press, and/or lay media if relevant of a corrective notice in terms approved by the Code Council/Appeals Board; the cost of this must be incurred by the company that is found to be in breach; (iv) Order the immediate publication of the decision in whole or in part and specify how and to whom the decision is to be sent. This is additional to inclusion of details of the decision in the annual Code of Practice Publication of Findings report (see Section 11 of this Annex); (v) Recommend to the IPHA Board of Directors suspension or expulsion from IPHA of the offending company; (vi) In the case of difficult and/or persistent breaches of the Code, refer the matter to the Minister for Health;

	This list is not exhaustive and other sanctions may be applied by the Code Council or Appeals Board as appropriate. In the event that the decision of the Code Council is appealed, the Appeals Board shall assume responsibility for the application of any or all or the above sanctions. In addition, the Appeals Board may uphold the decision of the Code Council but vary the sanctions applied.
18.	Annex I (Clause 12: who can propose a change): An amendment has been introduced so that rather than the general membership of an IPHA member company (or non-IPHA member signatory to the Code), only the Chief Representative of an IPHA member company, (or non-IPHA member signatory to the Code), may refer items for discussion to the IPHA. This is to avoid the situation where changes to the Code are proposed without the knowledge of the Chief Representative of that company. Other external groups, the Code Council and Appeals Board may still propose changes to the Code.
19.	Annex III (Clause 3: Patient Organisation [PO]): An amendment to the wording in this annex has been introduced to clarify that support such as donations and Grants (in cash or in kind or otherwise), significant indirect support or significant non-financial support to POs is only permitted under certain conditions (such as (i) it is made for the purpose of supporting healthcare, research or education; (ii) they are documented (written agreement)) and that the company shall not request, and the PO shall not undertake, the promotion of the companies' *prescription* medicines either directly or indirectly.
20.	Annex IV (Digital communication) Clause 2.3(iv): the following clarification has been made Where banner ~~or banner like~~ advertisements are in use, and if there is insufficient space on the electronic advertisement for all the information required (as set out in the Code), viewers must be either directed to click on the advertisement to bring them through to the required information, or a 'button' included on the advertisement containing the phrase "~~Abbreviated~~ Prescribing Information" (or similar wording).
21.	A new Clause 2.3 (v) has been added to Annex IV as follows to address the HPRA's previously raised concerns about balance. The requirement for balance is also detailed in the body of the Code. *The balance of safety and efficacy must be maintained at all times in digital advertisements and linking to the SmPC or other source of the relevant information does not preclude the need for the information contained in the advertisement itself to be balanced in terms of efficacy and safety.*
22.	Annex V (Clauses 2.1 & 3.5): The term *'subject to internal corporate compliance and feasibility'* has been removed from Clause 2.1 to avoid any ambiguity. Also, new wording has been introduced to Clause 3.5 to encourage members to move to Legitimate Interests as the legal basis for HCP disclosure. Each company shall document and publicly disclose Transfers of Value it makes, directly or indirectly on the IPHA Central Report (www.transferofvalue.ie), ~~*subject to internal corporate compliance and feasibility…*~~
23.	Annex VI (Advisory Boards; Clause 1.3) states that: *the internal attendees must be necessary and limited in number (not to exceed 50% of the number of external advisors. T*he following clarification has now been added: one note taker, or administrator, is additionally permitted provided that they only perform an administrative role in that meeting.
24.	Annex VI (Advisory Boards: Clause 1.4): The following has been added to Annex VI to align with the HPRA Guidance on this topic. During such meetings, the sponsor of the meeting should take action in situations where an advisor has made verbal statements at the meeting about a medicinal product which contradict, or are not in line with, the authorised Summary of Product Characteristics for the product, if one is in place. The sponsor should use their professional judgement when deciding how to react to such statements, but the goal of their action should be that the other attendees are not misled (intentionally or unintentionally) about the benefits or risks associated with a medicinal product. Reference to the HPRA's Guidance on Advisory Boards has also been added to this section of the Code.