Questions and Answers to the AIPM Code of Practice

1) ***Question:*** *What is the intended use of printed advertising materials and "reminder" advertising? And in what lies the difference between printed advertising materials and "reminder" advertising?*

Answer: Pursuant to the AIPM Code of Practice (hereinafter – "Code") "reminder" advertising is the variety of printed advertising materials.

Printed advertising material for healthcare professionals, as provided by sub-clause 3.2.1, and for general public, as provided by sub-clause 4.2.1, - it is the material containing true and complete information, which, as a whole, enables healthcare professionals or for consumers (patients) (for consumers/patients – only for over-the-counter pharmaceutical products) to get an idea of properties of the pharmaceutical product to the extent of its registered indications for use. Such material should contain information consistent with the requirements of sub-clauses 3.2.1 and 4.2.1 of the Code and in accordance with the requirements of the Federal Law "On advertising".

In the meantime, "reminder" advertising for healthcare professionals as provided by sub-clause 3.2.2, and for consumers (patients), as provided by sub-clause 4.2.2 (for consumers/patients – only for over-the-counter pharmaceutical products), - it is the material containing minimum information pursuant to the requirements of the Federal Law "On advertising" with the obligatory reference to the necessity of familiarization with the package leaflet or to obtain healthcare professional consultations. "Reminder" advertising material may contain the name of a pharmaceutical product (the trade name), therapeutic area of pharmaceutical product and/or brief information, such as slogan and/or key short message aimed exclusively at reminding of pharmaceutical product. However, this specified information should not induce expressly or implicitly to prescribe or to purchase pharmaceutical product, for example, by pointing at advantages of the product. Therefore, "reminder" advertising can be put at the particular place, where healthcare professionals or consumers (patients) have an opportunity to acquire additional information about product.

For example, in pharmacies, at the specialized exhibitions, congresses, conferences on billboards of pharmaceutical companies. For example, such type of advertising materials as "shelf talker", "wobblers", which are usually used in pharmacies and placed in close proximity to over-the-counter pharmaceutical products, may be defined as "reminder" advertising and characterized without limitation (inter alia) by the reason that in advertising location consumer/patient has direct access to the package leaflet or has an opportunity to obtain pharmacist/pharmaceutical professional consultations on properties characterization of over-the-counter pharmaceutical product.

2) ***Question:*** *What is meant by the term of "pharmaceutical product's launch"?*

Answer: Pharmaceutical product's launch – first actions of giving information to the healthcare professionals and/or patients on over-the-counter pharmaceutical product to the extent that these actions are taken by pharmaceutical company after the state registration of pharmaceutical product or of new indication for use within the territory of Russian Federation.

Examples of these actions are the following: launch of pharmaceutical product/or of new indication for use.

Besides, samples of pharmaceutical products may be provided to non-commercial medical organizations in the event that new indication for use is registered for treatment of another nosologic unit (pursuant to the ICD) or of a disease in another therapeutic area, or is aimed at treatment of particular groups of patients (for example children, patients with kidney or hepatic dysfunction and etc.). But at the same time variation of indications within the frame of the disease state and/or extent of disease may not be considered as a ground for providing samples.

Concurrently with the aforementioned, variation of pharmaceutical form may be considered as the sufficient ground for providing samples in exceptional circumstance when such variation leads to substantive change of administration route of pharmaceutical product. For example, parenteral use is added to the oral use. Therefore, healthcare professional is given an opportunity to obtain new experience in application of pharmaceutical product.

3) ***Question:*** *What is meant by "reasonable limits" in sub-clause 3.3.6 of the AIPM Code of Practice?*

Answer: For the purposes of sub-clause 3.3.6 of the Code, the term "reasonable limits" refers to the average cost of meals at events of such type (taking into account the duration of an event and number of participants) conducted by pharmaceutical companies in a particular region or in the whole country. AIPM member companies should have specific cost limits set by their internal documents.

4) ***Question:*** *Is it permitted to put company logos, trade names of pharmaceutical products and other components of a pharmaceutical company's product brands on the stationary items which may be provided at events according to sub-clause 3.3.5 of the AIPM Code of Practice?*

Answer: It is permitted to provide inexpensive stationery (pens, paper pads, and pencils) at events, for the purpose of taking notes or keeping records, only as long as these stationary items do not bear pharmaceutical company logos, trade names of pharmaceutical products or other components of a pharmaceutical company's product brands.

Comment: These restrictions will take effect on January 1, 2015.

5) ***Question:*** *How to disclose sponsorship fees paid to third parties, appointed by HCOs to manage the event (technical organizers).*

Answer: Under sub-clause 7.3.2 of the AIPM Code of Practice categories for transfers of value to HCO among others include contribution to costs related to events though HCO or third parties, including sponsorship agreements with third parties appointed by HCO to manage an event. The definition of the Transfers of Value provided by the AIPM Code apart from direct payment to HCO includes also transfers (whether in cash or in kind) to third parties, where company member could identify HCO that benefit from the transfer of value being a beneficiary.

When HCO appoints the technical organizer of the event, such technical organizer organizes an event using transfers of value received from sponsors for and under control of the HCO. Sponsorship fee paid to the technical organizer in this case shall be disclosed as transfer of value to the HCO, which appointed the technical organizer. As Transfers of value includes benefits in kind, disclosure does not necessarily means that HCO received money through the technical organizer; values in kind could be provided to HCO by technical organizer by means of renting the event facilities and financing other costs related to the event in HCO's interests.

The relations between technical organizer and HCO shall be properly documented, for example, by the trilateral agreement (company, HCO, technical organizer). If company concludes sponsorship agreement with technical organizer only, relations between HCO and such technical organizer (if available) shall be documented by such sponsorship agreement and confirmed by a document from HCO (e.g. letter by HCO).

6) ***Question:*** *How to disclose transfers of value to several HCOs appointed the one technical organizer to manage the event?*

Answer: Such transfers of value shall be disclosed based on the actual circumstances confirmed by documents. The exact distribution of the transfers of value among HCOs could be defined by the sponsorship agreement or by the official correspondence with such HCOs. The principles and methods used by company in preparing the disclosures, including specifications of allocation of transfers of value for the benefit of each HCO in accordance with AIPM Code of Practice, should be documented and can be published in the company's note summarizing such methodologies.

7) ***Question:*** *What is the meaning of "clearly identifiable Recipient" under* sub-clause *7.3.1 of the AIPM Code of Practice with respect to HCO?*

Answer: Companies have to ensure that HCO receiving the transfer of value is identified in such a way that there cannot be any doubt about the identity of the HCO receiving the Transfers of value.

In practical terms, there might be cases, where company pays sponsorship fee to the legal entity (not HCO), which independently organizes the event, not acting as an intermediate for any HCO. In this situation company cannot identify any HCO as Recipient of values and, correspondingly, disclosure is not required. Where the technical organizer is appointed by HCO and acts as an intermediary in HCO interests, payments to such technical organizer falls within the definition of the indirect transfer of value to HCO through the intermediary and, correspondingly, shall be disclosed.

The clear possibility to avoid doubts on the role and status of the party, to which sponsorship fee is paid, is to define such role and its relations with HCO (if any) in the sponsorship agreement. Such roles and status shall be confirmed by HCO by way of signing the sponsorship agreement (in case of trilateral agreement) or by a separate document (e.g. letter from HCO).

8) ***Question:*** *Whether it is permitted to distribute informational materials containing information on discount programs of pharmaceutical company designed to lower the cost both of prescription and over-the-counter pharmaceutical product for patients (hereinafter referred to as "Programs") in accordance with sub-clause 6.4.3 of the AIPM Code of Practice?*

Answer: Subject to any requirements provided by effective legislation of Russian Federation and AIPM Code of Practice pharmaceutical company or a third party hired by the pharmaceutical company should conclude a contract exclusively with the relevant pharmacy organizations, wherethrough the informational materials about the Programs are distributed for patients.

Compensation to pharmacy organizations should not be based on/related to the number of distributed materials and its parts.

Program materials should not be designed to draw attention to prescription pharmaceutical product, formation or maintaining of interest to the product and to promote it on the market. Additionally, advertising slogans of the company manufacturing pharmaceutical product, logo of the pharmaceutical product and other components of the pharmaceutical product's brand are prohibited for use.

In the event of Program materials are distributed in respect of prescription pharmaceutical product, pharmaceutical companies should ensure that such materials can be provided exclusively in return for prescription of HCP.

It is prohibited to distribute informational materials related to Programs for patients through and with the assistance of doctors.

9) ***Question:*** *What kind of event can be considered as international scientific event in accordance with sub-clause 3.3.3 of the AIPM Code of Practice?*

Answer: The event is considered to be truly international scientific event provided that the "international" status is conferred by its organizer mandatory defining it as "international" or an event with " international participation", the purpose of which is consists in sharing international scientific experience and international practice of innovative methods of treatment used by specialists from different countries.

10) ***Question:*** *Whether it is required to indicate the name of pharmaceutical company in the case of the disclosure of information about diseases and about their prevention in accordance with the clause 2.6 of the AIPM Code of Practice in the event that such indication may cause the risk of violation of the Russian Federation legislation?*

Answer: In the event when the indication of the name of pharmaceutical company in the case of the disclosure of information about diseases and about their prevention in accordance with the clause 2.6 of the AIPM Code of Practice may cause the risk of violation of the Russian Federation legislation, in accordance with the requirements of the AIPM Code the pharmaceutical company should apply the existing legislation of the Russian Federation.