Appendix 4
Questions and Answers to Section VII of the AIPM Code of Practice

Starting from 2016 the international pharmaceutical AIPM member-companies undertake to publish information on transfers of value made to or for the benefit of healthcare professionals and healthcare organizations.

ABOUT THE DISCLOSURE INITIATIVE

1. Wherefore was the initiative created?

In recent years the society pays more attention to the interaction of the pharmaceutical industry with healthcare professionals and healthcare organizations.

The pharmaceutical industry is committed to maintain open and fair interaction, demonstrating its commitment to transparency. This is a key element in building fruitful interaction to the benefit of patients.

The purpose of this initiative – to make the legitimate interactions of pharmaceutical companies and the medical society transparent and understandable to patients, government and the general public. Cooperation between the medical community and the pharmaceutical industry - the force for progress in medicine and healthcare.

Patients should be confident that these interactions do not affect the decisions of doctors, and healthcare professionals in making decisions on treatment are based only on the clinical data, their professional experience and interests of patients.

The task is to strengthen such legal relations by increasing their transparency to the benefit of patients.

2. Why was the initiative created?

Interaction of pharmaceutical companies and healthcare professionals are always necessary for the health of patients, and for the development of science. At the same time, today we can observe the increasing interest demonstrated by not only the public authorities, but also by society, to the substance of these interactions. Both want to be sure that this kind of interaction does not affect the doctor's decision of physician on the use of drugs and treatments.

In order to build confidence that the doctor decision is not biased, but objective and balanced, the international pharmaceutical industry has taken the initiative – to make the relationship between pharmaceutical companies and healthcare professionals understandable and transparent to the public. The path to ensuring that the interactions are open and transparent is a long process, which was prompted by some changes in the regulation as a whole. First of all, the need on the part of patients, as well as changes in the regulatory and legal environment in different countries, including the Russian Federation, were taken into account. So, in 2012 in Russia for the first time the rules on restrictions on the interactions between pharmaceutical companies and healthcare professionals, and rules on disclosure of conflict of interests have been introduced at the legislative level. The process of disclosure of transfers of value will be a logical continuation of the Russian legislation.

Remaining dedicated to its commitment to high ethical standards AIPM became a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA) in 2012. AIPM fully shares EFPIA position that there is necessity to ensure that interactions between pharmaceutical companies and society are not only conducted with integrity but are also transparent.

AIPM has therefore decided that its existing Code should be supplemented by requirements for detailed disclosure regarding the nature and scale of the interactions between pharmaceutical companies and healthcare professionals and healthcare organizations. AIPM expects that by taking this step it can enable public scrutiny and understanding of these relationships and thus contribute to the public confidence in the pharmaceutical industry.

3. What countries does the initiative cover?

The initiative to disclose transfers of value to healthcare professionals and healthcare organizations is supported by the representatives of the pharmaceutical industry and industry associations, both of developed and developing countries on the 5 continents of the globe.

These are the countries where there are communities that are members of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), including the Association of International Pharmaceutical Manufacturers (AIPM) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), brought together more than 30 national associations and 40 leading pharmaceutical companies.

4. Which companies support the initiative?

The initiative is supported by all member-companies of Association of International Pharmaceutical Manufacturers (AIPM). AIPM member-companies strongly believe that the initiative to disclose information about transfers of value will enhance mutual responsibility and ethical standards of interactions between the pharmaceutical industry and medical society and, ultimately, will serve the interests of patients and increase mutual trust in the eyes of society.

For the purposes of successful implementation of the transparency initiative there is need for understanding and broad cooperation of all stakeholders to strengthen the trust within the society as a whole, and between healthcare professionals and pharmaceutical industry, in particular.

5. Legal basis of interactions between the industry and medical society.

In accordance with legislation on interactions between pharmaceutical industry and medical society healthcare professionals are not prohibited to participate in professional scientific events organized and (or) sponsored by pharmaceutical companies, and healthcare professionals being the medical professionals are not prohibited to receive remuneration under the contracts in the course of performance of clinical trials, remuneration associated with educational and (or) scientific activities of medical professionals.

6. Who and how will have access to the disclosed data?

Each AIPM member-company will publish disclosed data on the relevant pharmaceutical company's website unrestricted and publicly available. Therefore, the data will be available for general public.

7. When the disclosure of transfers of value will be published?

Obligations to disclose information on the transfer of values provided for in Chapter VII of the Code come into force in the year 2016 (with the provision of data for the year 2015). Thus, pharmaceutical

companies-members of the AIPM undertake to publish data for the year 2015 on the transfers of value made by the companies from June 20 to June 30, 2016 on their websites. Starting from the year 2016, disclosures must be made by each AIPM member company on an annual basis, and each reporting period must cover a full calendar year.

8. Where the published information on transfers of value can be found?

Disclosure of information will be published on the relevant pharmaceutical company's website making transfers of value, or on the corporate web-site of the Group of companies which incorporates the respective company (in the event of absence of the own company's web-site).

GENERAL PROVISION OF DISCLOSURE

9. Who shall disclose transfers of value?

Each pharmaceutical company shall document and disclose transfers of value it makes, directly or indirectly, to or for the benefit of any healthcare professional or healthcare organization being a recipient of transfers of value.

10. What is the meaning of transfers of value in accordance with the AIPM Code of Practice?

Transfers of value in the frame of the initiative - direct and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for the purposes permissible by the applicable legislation and by this Code in connection with the development and sale of exclusively prescription-only pharmaceutical products for human use.

Direct transfers of value are those made directly by a pharmaceutical company for the benefit of a recipient.

Indirect transfers of value are those made on behalf of a pharmaceutical company for the benefit of a recipient, or transfers of value made through an intermediate (e.g. event organizing agency) and where the pharmaceutical company knows or can identify the healthcare professional/healthcare organization that will benefit from the transfer of value

11. What transfers of value should be disclosed?

The following transfers of value should be disclosed:

I. Donations and grants to healthcare organizations that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organizations or associations that are comprised of healthcare professionals and/or that provide healthcare.

II. Contribution to costs related to events. Contribution to costs related to events, through healthcare organizations or third parties such as:

- Registration fees;
- Sponsorship fees under agreements with healthcare organizations or with third parties appointed by a healthcare organization to manage an event; and
- Travel and accommodation.

III. Fees for service and consultancy. Transfers of value resulting from or related to contracts between pharmaceutical companies and healthcare professionals and/or healthcare organizations under which such healthcare professionals and/or healthcare organizations provide any type of

services to a pharmaceutical company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand transfers of value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

IV. Contribution to costs related to events and participation of healthcare professionals therein

- Registration fees;
- Travel and accommodation.

V. Research and development transfers of value.

12. Shall each transfer of value be disclosed on an individual basis, for each clearly identifiable recipient?

Each transfer of value shall be disclosed on an individual basis provided that applicable data protection, including personal data protection rules of Russian legislation are complied with. Specifically, each pharmaceutical company shall disclose the amounts attributable to each category of transfers of value to or for the benefit of healthcare professionals and healthcare organizations being a recipient on an individual basis for each clearly identifiable recipient.

The exception is provided by the following categories of transfers of value which are disclosed on an aggregate basis:

A) Research and development transfers of value;

B) Transfers of value to healthcare professionals in the event when healthcare professional doesn't give consent to individual disclosure of transfers of value or withdrew it;

C) to the extent otherwise provided by legislation

13. What transfers of value should not be disclosed?

The following transfers of value made in accordance with effective legislation and AIPM Code of Practice should not be disclosed:

(i) transfers of value that are solely related to over-the-counter pharmaceutical products;

(ii) transfers of value that are not listed in the answer to the question 11 (eleven), such as:

- i tems of medical utility,
- meals and drinks,
- samples of the pharmaceutical products; or

(iii) transfers of value that are part of ordinary course purchases and sales of pharmaceutical products by and between a pharmaceutical company and a healthcare organization, as relevant.

14. How often shall the transfers of value be disclosed?

Starting from the year 2016 disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year.

Disclosures shall be made by each pharmaceutical company within 6 (six) months after the end of the relevant reporting period and the information disclosed shall be required to remain in the

public domain for a minimum of 3 (three) years after the first disclosure of such information, unless otherwise is required under current national data privacy law and other applicable national regulations.

15. How will transfers of value be disclosed?

For consistency purposes, disclosures will be made using a unified template together with synchronous publication of the note summarizing the methodologies used in preparing the disclosures.

16. The currency of disclosed transfers of value?

Taking into account that Association represents the interests of international pharmaceutical companies on the territory of the Russian Federation it is expected that member-companies will disclose transfers of value in rubles.

TRANSFERS OF VALUE TO OR FOR THE BENEFIT OF HEALTHCARE PROFESSIONALS

17. Who are considered to be healthcare professionals in accordance with the AIPM Code?

Pursuant to the provisions of the AIPM Code healthcare professionals – doctors and other medical professionals, heads of medical organizations, pharmaceutical professionals (including pharmacists), heads of pharmacy organizations, and other specialists the professional activity of which is concerned with pharmaceutical products and who in the process of their professional activity have the right to prescribe, recommend, purchase, supply, or administer pharmaceutical products.

18. How the transfers of value are disclosed?

In disclosing transfers of value to or for the benefit of healthcare professionals the data should be published exclusively subject to the effective Russian legislation requirements on personal data protection, provided that healthcare professionals gave the appropriate written consent and in compliance with other requirements established by the law.

Disclosure is made in accordance with the structure set forth in Appendix 2 to the AIPM Code of Practice. If there is no consent or the consent is withdrawn disclosure of transfers of value to healthcare professionals should be made on an aggregate basis without identification of specific recipients of transfers of value.

19. Whether a company refuses further interactions with healthcare professional if he doesn't give consent to individual disclosure with identification of specific recipient?

The question of further interactions with healthcare professional in the event when healthcare professionals do not grant consent to disclose payments on and individual basis is under an individual company decision in accordance with their own policies and criteria for working with healthcare professionals in accordance with the applicable Russian legislative frameworks.

20. How should disclosure be managed where the Recipient gives partial consent? For example, where consent is given for the consultancy fees to be disclosed, but not associated payments for travel & accommodation, being the essential part of the contract?

Member-companies are encouraged to ensure the absence of ambiguity of provisions of the contract and consent notice concluded in the frame of interaction with healthcare professionals.

If notwithstanding the Member Company's efforts a Recipient gives only partial consent to any provisions of the specific contract Transfers of Value of the Member Company made to that Recipient in accordance with the contract should be declared in the aggregate disclosure subject to applicable legislation of the Russian Federation.

Partial disclosure under the individual disclosure category would be misleading with respect to the nature and scale of the interaction between the Member Company and the Recipient.

21. Whether there is a requirement to have consent of healthcare professional in accordance with the Code requirements if the healthcare professional is the sole proprietor?

Taking into account that healthcare professional registered as the sole proprietors are considered to be personal data subjects it is requisite to receive the relevant written consent to personal data processing and disclosure. If the consent was not received the disclosure should be made on an aggregate basis.

TRANSFERS OF VALUE TO OR FOR THE BENEFIT OF HEALTHCARE ORGANISATIONS

22. Who are considered to be healthcare organizations in accordance with the AIPM Code?

Pursuant to the provisions of the AIPM Code healthcare organizations – any legal entity (i) that is a healthcare, medical, pharmaceutical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution (except for patient organizations) whose business address, place of incorporation or primary place of operation is in Russia or (ii) which provides services through one or more healthcare professionals.

23. How to disclose sponsorship fees paid to third parties, appointed by HCOs to manage the event (technical organizers)?

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).

24. How to disclose transfers of value to several HCOs appointed the one technical organizer to manage the event?

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.

25. What is the meaning of «clearly identifiable Recipient» under sub-clause 7.3.1. of the AIPM Code of Practice with respect to HCO?

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).

26. Whether there is a requirement to receive the consent of healthcare organizations to disclose the data on transfers of value?

There is no requirement to receive the consent of healthcare organizations to disclose the data on transfers of value provided that the relevant disclosed data fails to appear as the State secret, banking, commercial secrecy or other such other protected information in accordance with legislation of the Russian Federation. Alongside with that, in the event when in accordance with conditions of the contract there are limitations and/or prohibition to disclose information on transfers of value to or for the benefit of healthcare organizations, it is recommended to make the renegotiation of provisions of the contract in accordance with proposed form «Disclosure clause in contract templates with HCOs», which is provided below, and inform healthcare organization on the rules of disclosure on an individual basis for each clearly identifiable healthcare organization by inclusion of the certain conditions into the contract or through another means.
<<< Disclosure clause in contract templates with HCOs

The parties acknowledge that being a member of the Association of International Pharmaceutical Manufacturers (AIPM) and in accordance with the AIPM Code of Practices the Company is quiredto publically disclose certain information to enhance transparency, such as donations and grants, payments of fee for services, sponsorships agreements or contribution to costs of events, representing a transfer of value made to healthcare organisations by pharmaceutical companies. [HCO name as defined in the contract] hereby gives its consent to the Company to report and disclose on an individual basis (naming the [HCO name as defined in the contract] in the disclosure materials) any information on any transfers of value to [HCO name as defined in the contract] under this agreement and any related information in accordance with the laws and self-regulation in

force, both during the term of this agreement and afterwards. Detailed information on transfer of value to individual healthcare organization can be accessed through a secure website.

27. Shall the sponsorship fees related to the conduct of events organized by the Ministry of Health, its region and/or competent divisions, being the State bodies, be disclosed?

State bodies are not considered to be the «Healthcare organizations» in accordance with definition provided by the AIPM Code of Practice. Therefore, sponsorship fees related to the conduct of events organized by the State bodies should not be disclosed. In the meantime, in the event when the official scientific professional event is conducted under the patronage and/or with the support of such State bodies as the Ministry of Health, its region and/or competent divisions in accordance with the approved plan of events, and healthcare organizations presented without limitation as professional medical associations and such organizations are acting as organizers in idea, contribution to costs related to the conduct and organizing of such events should be disclosed as transfers of value to the specified healthcare organizations.

28. Shall the payment of the state duty and other mandatory payments dedicated to satisfying the requirements provided in the frame of state marketing authorization procedure, certification of pharmaceutical products be disclosed?

Transfers of value related payment of the state duty and other mandatory payments made by companies in the process of marketing authorization, expertise, certification and other procedures prescribed by the law should not be disclosed.

RESEARCH & DEVELOPMENT TRANSFERS OF VALUE

29. What is the meaning of Research and development transfers of value for the purposes of enforcing disclosure obligation?

Research and development transfers of value) - transfers of value to healthcare professionals or healthcare organizations related to the planning or conduct of (i) pre-clinical studies; (ii) clinical trials; or (iii) post-registration observation (non-interventional) studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, healthcare professionals specifically for the study, including without limitation transfers of value to healthcare organizations under clinical trial agreement, including laboratory and instrumental investigations; fees for the providing of scientific and/or pedagogic services by healthcare professional being a edical professional and services in the course of performance of clinical studies.

30. How the Research and development transfers of value shall be disclosed?

Research and development transfers of value in each reporting period shall be disclosed by each pharmaceutical company on an aggregate basis. Costs related to events that are clearly related to activities covered in the answer to the question 29 also can be included in the aggregate amount under the «Research and Development Transfers of Value» category.

31. How the Research and development transfers of value which are out of the scope of the Code definition regarding Research and development transfers of value provided by the Code and specified in the answer to the question 29 shall be disclosed?

Transfers of value that do not fall within the definition of «Research and Development Transfers of Value» for the purposes of disclosure obligation enforcement, specified in AIPM Code and in the answer to the question 29 shall be disclosed under the category «fee for service and consultancy».

32. Why do the retrospective non-interventional studies fall under the individual disclosure category?

Following the AIPM Code the definition of R&D Transfers of Value in the clause 1.2. retrospective non-interventional studies do not fall within the scope of the definition of R&D Transfers of Value. Transfers of Value relating to retrospective non-interventional studies shall be disclosed under the name of the individual Recipient. If companies cannot differentiate the retrospective and prospectives non-interventional studies, they ought to disclose all the non-interventional studies in individual.

33. Is a clinical research organization (CRO) a HCO?

A CRO is not an HCO for the purposes of chapter VII of the Code. A clinical research organization (CRO) is an organization that provides support in the form of research services outsourced on a contract basis with a company. However, Member Companies in the process of Transfers of Value to HCPs/HCOs through CROs - such indirect payments are within the scope od Disclosure requirements in accordance with the Code.

As a rule, each Member Company will decide on the inclusion of Transfers of Value to CROs into the different categories of disclosure.

If activities contracted to CROs fall within the scope of the definition of R&D Transfers of Value provided in the Code, they will be part of the aggregate disclosure under that category. Otherwise, they will be reported under the relevant category specified in sub-clauses 7.3.2. and 7.3.3. of the Code.

In their written contracts with CROs, Member Companies are encouraged to include provisions relating to the CROs' consent to disclose Transfers of Value that will ultimately benefit HCPs/HCOs in accordance with the provisions of the Code.

In the Methodology Note, the Member Company is encouraged to provide additional clarification on the nature of the Transfers of Value included.