

ASSOCIATION OF INNOVATIVE PHARMACEUTICAL MANUFACTURERS (AIPM) TRANSPARENCY
CODE ON THE DISCLOSURE OF TRANSFERS OF VALUE FROM AIPM COMPANIES TO
HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANIZATIONS
("TRANSPARENCY CODE")

PREAMBLE TO THE TRANSPARENCY CODE

The Companies believe that cooperation between the pharmaceutical industry and healthcare professionals has a profound and positive influence on the quality of patient treatment and the value of future research. The Companies recognize that cooperation between the industry and healthcare professionals can create the potential for conflicts of interest. Consequently, professional and industry associations, including the Companies, have adopted Transparency Codes and guidelines to ensure that these interactions meet the high standards of integrity expected by patients, governments and other stakeholders.

In order to continue to be successful, self-regulation needs to respond to the evolving demands of the society. In particular, there is a growing expectation that cooperation between corporations and society is not only conducted with integrity, but is also transparent.

In line with these "Guiding Principles", the Companies believe that it is critical to the future success of the pharmaceutical industry to respond to society's heightened expectations. The Companies have therefore decided that their existing Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals should be supplemented by a Transparency Code defining requirements for detailed disclosure regarding the nature and scale of the interactions between the industry and healthcare professionals and organizations. The Companies hope that by taking this step, they can enable public scrutiny and understanding of these relationships and thus contribute to the confidence of stakeholders in the pharmaceutical industry.

The Companies believe that the interest of patients and other stakeholders in the transparency of these interactions is compelling. Due to its nature, the Transparency Code, serving the purposes of self-regulation, defines stricter requirements than legislation.

The following code imposes obligations to disclose transfers of value commencing with reporting in 2016 in respect of transfers of value for the calendar year 2015. The provisions of this Transparency Code shall be implemented by the Companies in a manner consistent with applicable competition and data protection laws and regulations and all other applicable legal requirements.

The Transparency Code complies with the requirements defined in the European Federation of Pharmaceutical Industry Associations (EFPIA) Code on the disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organizations.

This Transparency Code has been approved by the AIPM General Assembly; only the General Assembly has the right to amend this Transparency Code, but the General Assembly shall authorize the AIPM Executive Committee to amend and align the Transparency Code as necessary within its own competence whenever changes to relevant legislation occur.

AIPM Companies and other companies adopting the Code accept the verbatim requirements set out herein and the spirit of the Transparency Code as binding upon them*.

Budapest, 2013.12.12.



Dr. Jakab Zoltán



Frequently used terms and abbreviations

(in line with the definitions of the Code of Ethics for Pharmaceutical Marketing Communications)

HCP	Healthcare personnel (doctor, pharmacist, healthcare assistant, member of health service provider staff or any other specialist) qualified to recommend, prescribe, procure, sell, supply or administer medicinal products and involved in patient care except employees of pharmaceutical manufacturers, distributor and wholesalers.
Company(ies)	Member companies of the Hungarian Association of Innovative Pharmaceutical Manufacturers and their subsidiaries or affiliates, and any other pharmaceutical manufacturer, wholesaler or distributor that is a signatory of this Transparency Code and has accepted it as binding upon it in a declaration of adherence.
Event	All promotional, scientific or professional events within the meaning of Act XCVIII of 2006 on the Safe and Economical Supply of Medicinal Products and Medical Devices and the General Rules of Medicine Distribution sponsored by or on behalf of a Company or meetings with an HCO representative or an HCP (collectively: "Event") with the participation of an HCO representative or an HCP, the costs of which are covered by a Transfer of Value provided by the Company either directly or indirectly, with or with no services rendered in exchange.
HCO	Any healthcare service provider within the meaning of the act on healthcare or any organization through which Transfers of Value are directly or indirectly made to HCPs. Patient organizations and pharmaceutical manufacturers, distributors and wholesalers are not considered HCOs. Patient organizations, pharmaceutical manufacturers, distributors and wholesalers form exceptions.
Recipient	Any HCP or HCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Europe.
Research and Development Transfers of Value	Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice and in the acts on healthcare and medicinal products); (ii) clinical trials (as defined in the acts on healthcare and medicinal products); or (iii) 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, HCPs specifically for the study.
Transfers of Value	Direct and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only Medicinal Products exclusively for human use. Direct transfers of value are those made directly by a Member Company for the benefit of a Recipient. Indirect transfers of value are those made on behalf of a Company for the benefit of a Recipient, or transfers of value made through an intermediate and where the Company knows or can identify the HCP/HCO that will benefit from the Transfer of Value.

SCOPE OF THE TRANSPARENCY CODE

This Transparency Code governs disclosures regarding Transfers of Value to HCPs and HCOs in the context of commercial practices and Research and Development carried out in Hungary. This Transparency Code governs disclosures regarding Transfers of Value to HCPs and HCOs in the context of interactions, in harmony with the existing provisions of the Code of Ethics for Pharmaceutical Marketing Communications. The definitions used in this Transparency Code shall be interpreted in line with the definitions set out in the Code of Ethics for Pharmaceutical Marketing Communications.

The disclosure obligation defined in Section 1 does not apply to Transfers of Value related to over-the-counter (OTC) medicines, supply of assets for medical and educational purposes within the meaning of Section 10.1 of the Code of Ethics for Pharmaceutical Marketing Communications, inexpensive meals, supply of free samples to physicians within the meaning of Section 15 of the Code of Ethics for Pharmaceutical Marketing Communications and Transfers of Value related to the regular pharmaceutical procurement and sales processes between a Company and an HCP (such as pharmacists)/HCO.

ENFORCEMENT OF THE TRANSPARENCY CODE

The Companies shall do everything in their power to fully adhere to the requirements of this Transparency Code at all times. If there is an inconsistency between this Transparency Code and the applicable law or regulation to which a Company is subject which would render adherence to this Transparency Code not possible, the Company must comply with such law or regulation and such lack of adherence shall not constitute a breach of this Transparency Code.

Non-AIPM Companies that decide to voluntarily implement this Transparency Code and issue a declaration of adherence shall require that each of their respective members, affiliates and subsidiaries, as applicable, comply with all of the provisions of this Code.

ARTICLE 1 DISCLOSURE OBLIGATION

Subject to the terms of this Transparency Code, each Company shall document and disclose Transfers of Value it makes, directly or indirectly, to or for the benefit of a Recipient, as described in detail in Section 3.

ARTICLE 2 FORM OF DISCLOSURE

Section 2.01 *Annual disclosure.* Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year (the "Reporting Period"). The first Reporting Period shall be the calendar year 2015.

Section 2.02 *Time of Disclosure.* Disclosures shall be made by each Company within 6 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 years after the time such information is first disclosed, unless, in each case, (i) a shorter period is required under applicable data privacy or other laws or regulations, or (ii) the Recipient's consent relating to a specific disclosure has been revoked.

Section 2.03 *Form of Disclosure.* Subject to Section 2.04(ii), for consistency purposes, disclosures pursuant to this Code will be made using a structure set forth in Schedule 1 for reference.

Section 2.04 *Platform of Disclosure.* Disclosures can be made in a manner ensuring that they are unrestricted and publicly available.

Section 2.05 *Geographic and Personal Scope.* Disclosures shall be made pursuant to the national code of the country where the Company has its physical address, irrespective of the nationality of the HCP or the HCO.

Section 2.06 *Language of Disclosure.* Disclosures shall be made in Hungarian, and may optionally be published in English as well.

Section 2.07 *Storage and Archiving.* Each Company shall document all Transfers of Value required to be disclosed pursuant to Section 1 and maintain the relevant records of the disclosures made under this Transparency Code for a minimum of 5 years after the end of the relevant Reporting Period, unless the Recipient has revoked its consent to the handling of its data or a shorter period is required under applicable national data privacy or other laws or regulations.

ARTICLE 3

INDIVIDUAL AND AGGREGATE DISCLOSURE

Section 3.1 *Individual Disclosure.*

Except as expressly provided by this Transparency Code, Transfers of Value shall be disclosed on an individual basis, specifying the name of the Recipient HCP or HCO. Each Company shall disclose, on an individual basis for each clearly identifiable Recipient, the amounts attributable to Transfers of Value to such Recipient in each Reporting Period which can be reasonably allocated to one of the categories set out below. Such Transfers of Value may be aggregated on a category-by-category basis, provided that itemized disclosure shall be made available upon request to (i) the relevant Recipient, and/or (ii) the relevant authorities.

3.1.1 For Transfers of Value to an HCO, an amount related to any of the categories set forth below:

- a) Donations and Grants to HCOs that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organizations or associations that are comprised of HCPs and/or that provide healthcare (governed by Article 11 of the Code of Ethics for Pharmaceutical Marketing Communications).
- b) Contribution to costs related to Events*, through HCOs or third parties, including sponsorship to HCPs to attend Events. These may include:
 - a. registration fees;
 - b. sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event; and
 - c. travel and accommodation.
- c) Transfers of Value resulting from or related to contracts between Companies and research institutions, organizations or associations of HCPs, healthcare service providers, professional organizations of HCPs or any other organizations linked to healthcare under which such institutions, organizations or associations provide any type of services to a Company or any other type of funding not covered under items a) or b). 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.

3.1.2 For Transfers of Value to an HCP:

- a) Contribution to costs related to Events*, such as:
 - a. registration fees; and
 - b. travel and accommodation.
- b) Transfers of Value resulting from or related to contracts between Companies and HCPs under which such HCPs provide any type of services or consulting to a 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.

Section 3.2 *Aggregate Disclosure*

For Transfers of Value where certain information, which can be otherwise reasonably allocated to one of the categories set forth in Section 3.1, cannot be disclosed on an individual basis for legal reasons, a Company shall disclose the amounts attributable to such Transfers of Value in each Reporting Period on an aggregate basis. Such aggregate disclosure shall identify, for each category, (i) the number of Recipients covered by such disclosure, on an absolute basis and as a percentage of all Recipients, and (ii) the aggregate amount attributable to Transfers of Value to such Recipients.

Section 3.3 *Non Duplication*

Where a Transfer of Value required to be disclosed pursuant to Section 3.1 or 3.2 is made to an individual HCP indirectly via an HCO, such Transfer of Value shall only be required to be disclosed once. To the extent possible, such disclosure shall be made on an individual HCP named basis pursuant to Section 3.1.2.

Section 3.4 *Transfers of Value related to Research and Development*

Companies shall publish aggregate reports on Transfers of Value related to Research and Development for each reporting period. Costs related to Events* that are clearly related to activities covered in this section (registration, accommodation, travel) can be included in the aggregate amount under the "Research and Development Transfers of Value" category.

Section 3.5 *Methodology*

Each Company shall publish a note summarizing the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each category described in Section 3.1. The note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Transfers of Value for purposes of this Code, as applicable.

ARTICLE 4

IMPLEMENTATION AND PROCEDURE RULES

The Implementation and Procedure Rules set out in this Article establish the framework for the support and implementation of the Transparency Code, the handling of procedures in violation of the Transparency Code and the conditions of enforcement of legal sanctions.

The Companies shall set up a Transparency Committee tasked with overseeing compliance with the Transparency Code, defining its functions and its rules of procedure for handling conduct infringing the Transparency Code.

Section 4.1 *Appointing the members and Chair or the Transparency Committee, the role and competence of the Chair*

The Transparency Committee consists of four (4) members of the Ethic Committee for Communications elected pursuant to the Code of Ethics for Pharmaceutical Communication. The rules of procedure set out in the Code of Ethics for Pharmaceutical Communication shall apply to their appointment.

If the legal status of any Transparency Committee member should cease on any grounds whatsoever, a new member shall be appointed within 30 days.

Members of the Transparency Committee shall appoint a Chair at its founding meeting. The Chair's mandate applies to its Communication Ethical Committee mandate as defined in the Code of Ethics for Pharmaceutical Communication. The Chair may be re-elected twice.

The Chair shall:

- convene and chair the meetings of the Transparency Committee;
- draft, document and send Transparency Committee resolutions to the affected parties; publish such resolutions;
- Check the execution of resolutions;
- Representation of the Transparency Committee

Section 4.2 *Transparency Committee functions related to the Transparency Code*

- a. The Transparency Committee shall hold a consultation with the representatives of the Companies at least once a year in order to develop the Transparency Code and to foster the ethical conduct of the Companies, in the context of which participants can share their experiences and comments on the application of the Transparency Code. The Transparency Committee shall summarize the findings established at the consultation in its Annual Report specified in item b).
- b. The Transparency Committee shall draw up an Annual Report on the implementation of the Transparency Code, covering:
 - A summary of the activities performed by the Transparency Committee during the year under review, including procedures for the violation of the Transparency Code and the findings of such procedures;
 - the comments and findings specified in item a) in connection with the implementation of the Transparency Code;
 - recommendations for the development and modification of the Transparency Code with the intention of increasing transparency and integrity within the Companies.
- c. The Transparency Committee shall conduct the procedures defined in Section 4.3 in the event of any violation of the Transparency Code;
- d. The Transparency Committee shall assist the Companies in meeting their obligations set out in this Transparency Code by publishing its positions on the implementation of the Transparency Code. The Transparency Committee shall review its positions on the Transparency Code and its interpretation and execution on a regular basis.

Section 4.3 *Transparency Committee procedures applicable to violations of the Transparency Code*

The Transparency Committee shall initiate procedures in response to complaints or ex officio in the cases discovered by it.

When adjudicating cases opened on account of violations of the Transparency Code (“**Transparency Procedure**” or “**Procedure**”), the Transparency Committee member having lodged the complaint or affected by the report or the employee of the Company under an ex officio procedure or biased on any other grounds and thus incapable of objective assessment shall not take part in the case. Adjudication of a transparency procedure is understood to mean participation in the proceedings, actual decision-making and any appeals procedure. If the Chair of the Transparency Committee is employed by the party having lodged the complaint or subject to the procedure, the members of the Transparency Committee shall appoint a presiding chair to conduct the procedure instead.

Complaints may be lodged by the Companies (including their employees), as well as other companies, organizations and natural persons. The Transparency Committee shall ensure that complaints lodged by the Companies or other entities are adjudicated based on equal terms.

The Transparency Committee shall examine the complaint, its well-foundedness and decide whether to launch a procedure. If the complaint is lacking any data or evidence required for establishing whether the Transparency Code has been violated, the Transparency Committee shall issue a single request for supplementary data or evidence to the complaining party, setting a deadline for supplying such data or evidence. If the complaining party fails to meet this requirements, the complaint shall be dismissed. The Transparency Committee shall also dismiss complaints that are clearly not aimed at compliance with the Transparency Code or in respect of which the Transparency Committee lacks competence, or a judgment has already been issued or is pending on the case.

If the Procedure is well-founded, the Transparency Committee shall open proceedings and notify both the complaining party and the reported Company (specifying the conduct at issue) in writing.

The Transparency Committee may request additional information needed for elucidating the circumstances of the case from both the complaining party and the Company under review.

If the Transparency Committee opens ex-officio proceedings, it shall notify the affected Company of the conduct or action it has identified as presumably violating the Transparency Code.

Procedures may be instituted within one year of the violation of the Transparency Code, however if the infringement is in the form of omission, the procedure may be instituted during the violation and within the year following its remedy.

The Chair shall convene a KEB meeting within thirty (30) days of receiving a new complaint or on a monthly basis for pending issues by the tenth day following notification at the earliest, simultaneously dispatching the documents of the Procedure.

The meeting is quorate if at least three (3) members are present. If a regularly convened Transparency Committee meeting does not have a quorum, the Chair shall convene a new Transparency Committee meeting again within seven (7) days and repeat this as long as the Transparency Committee meeting has a quorum. If the Chair is absent, the members of the Transparency Committee shall appoint a presiding chair. The Transparency Committee makes its decisions based on the documents and other materials necessary for assessing the case, hearing the party subject to the procedure. The Transparency Committee shall pass its decisions with a simple majority of votes. In the case of a tie vote, the chairperson's vote shall be decisive.

Section 4.4 *Transparency Committee decisions*

The Transparency Committee issues substantive decisions on conduct that is in violation of the Transparency Code and applicable sanctions by virtue of a resolution or by terminating the Procedure by virtue of a ruling if no violation has been established or the procedure was unfounded, or if the case is no longer relevant. The Transparency Committee decision concluding the procedure shall present the facts revealed, the decision (operative clause), its reasoning and any sanctions applied.

The Transparency Committee may apply the following sanctions (or a combination of sanctions) in the event of any violation of the Transparency Code:

- a. warn the infringing Company in writing;
- b. request the infringing Company to cease its conduct and to align its conduct with the provisions of the Transparency Code by the stated deadline and in the defined manner, and notify the Transparency Committee in writing within the deadline of the steps taken;
- c. In the event of serious or repeated offences violating the Transparency Code, the resolution shall be published on the website of the Association of Innovative Pharmaceutical Manufacturers/the Transparency Committee mentioning the name of the infringing Company until the conduct is remedied, but for no more than one year from the issuance of the resolution;
- d. in the event of very serious or several repeated offences, the Company shall be excluded and its name published on the website of the Association of Innovative Pharmaceutical Manufacturers/the Transparency Committee and the Hungarian Medical Chamber/Hungarian Chamber of Pharmacists among "Non-Transparent Pharmaceutical Manufacturers" until the conduct is remedied;

Publication within the meaning of item d) shall be posted on the section of the websites accessible not only to registered users, but to the public sections of the websites of the Association of Innovative Pharmaceutical Manufacturers/the Transparency Committee and the Hungarian Medical Chamber/Hungarian Chamber of Pharmacists, without violating any personal data or trade secrets.

Section 4.5 *Appeal against Transparency Committee decisions*

Requests for the revision of Transparency Committee resolutions can be made to the Director of the AIPM within 15 days of receipt of the resolution ("Appeal"). Appeals against rulings may be lodged by the complaining party within 8 days. Appeals shall be lodged to the Transparency Committee. The Director of the AIPM shall convene a three-member ad-hoc revision committee. Members of the ad-hoc committee are appointed by the Director of the AIPM from among AIPM Board members.

The committee appoints a presiding chair among its members who will set out the committee's resolution in writing.

Regular Transparency Committee members cannot take part in the ad hoc committee's meetings. The ad hoc committee makes its decision based on the documents of the procedure but may, as necessary, hear the affected parties at its own initiative or do so at the request of either of the affected parties.

The committee's resolution is final. The committee shall notify the affected parties, the Transparency Committee and the Companies in writing, and the Companies can also publish such resolution.

ARTICLE 5 AMENDMENT OF THE TRANSPARENCY CODE

The AIPM accepts amendment proposals to the Transparency Code following approval by the AIPM Board/Executive Committee, in line with the rules of procedure of its General Assembly.