TRANSPARENCY CODE

of the INFARMA Employers' Union of Innovative Pharmaceutical Companies

KODEKS Przejrzystości

INFARMA
Związek Pracodawców
Innowacyjnych Firm Farmaceutycznych

TRANSPARENCY CODE of the INFARMA Employers' Union of Innovative Pharmaceutical Companies

Preamble

The Transparency Code governs disclosures regarding cooperation between healthcare professionals and healthcare organisations. We wish this permanent cooperation, subject to the strict rules of good practice in our sector, to be treated in accordance with its essence: as a natural element of the healthcare system. Such cooperation is necessary for the entire system to fulfil its role for the patient.

We, Signatories of the Transparency Code, emphasise that the healthcare system must be transparent, and that its rules and requirements must be perfectly comprehensible for citizens. This is one of the main conditions of public confidence in all institutions which are part of that system, including us: the socially responsible and committed pharmaceutical companies.

The development, manufacturing and marketing of medicines is the fundamental responsibility of pharmaceutical companies towards patients, physicians and all other healthcare professionals who are to ensure safe medical treatment. Medicine research, conducted in accordance with Good Clinical Practice as well as broad knowledge of their effects, represents the basis of proper pharmacotherapy. No effective and safe medicine can be developed without research and cooperation with experts. We are obliged to take all suggestions into careful consideration, and share our experience with all physicians. Our primary goal is to provide the patient with assistance at the highest possible level. Pharmaceutical companies take their responsibilities very seriously, and thus feel obliged to provide financial and organisational support for the system of post-graduate educational programmes for physicians, especially in fields which are not directly linked to pharmacotherapy, but refer to broad medical knowledge.

In view of the foregoing, and of the public interest, pharmaceutical companies have decided to develop the Transparency Code, which will embody the concept of an open society with sustainable mechanisms of public accountability.

Our intention was that the Transparency Code would provide for the presentation of the scope, the accurately estimated value and importance of cooperation between pharmaceutical companies, and healthcare professionals and healthcare institutions. The cooperation involves, for example, scientific meetings, congresses, promotional meetings, conferences, training workshops and other similar events, including advisory groups meetings, visits to research institutions and manufacturing plants, as well as meetings dedicated to clinical trials. Each element of the healthcare system has its own specific value, whether it is a patient's standard visit to a General Practice Doctor, or a professional opinion on a specific aspect of a medicine's effects. The beneficiaries of the healthcare system have the right to (and definitely should) be aware of that value, and understand the meaning of factors which affect their therapy.

Cooperation with pharmaceutical companies, as well as the system of compensation for the specialists extra work, must be governed by clear, uniform rules. Pursuant to the Transparency Code, the Signatories undertake to publish information about the value and type of material cooperation with healthcare professionals and healthcare organisations. Upon notifying healthcare professionals and healthcare organisations and obtaining their consent, the Signatories of the Transparency Code will publish such information on their websites.

By making necessary investments, we improve Polish standards of medical treatment, and want to build the confidence of patients, who have the right to receive prompt and effective therapy. We, Signatories of the Transparency Code, wish to make this clear for all the recipients of information we publish. The full confidence of patients in doctors' competence and the effectiveness of their recommendations is the absolute foundation of proper medical treatment.

Chapter I

GENERAL PROVISIONS

Article 1

Subject matter of the Transparency Code

The Transparency Code governs disclosures regarding cooperation between healthcare professionals and healthcare organisations on one side, and Signatories of the Transparency Code on the other, as well as the related Transfers of Value.

Article 2

Definitions

For the purpose of the Transparency Code, the terms listed below shall have the following meanings:

1. Donations

Donations, grants and other benefits provided free of charge, including cash and benefits in kind, as defined under Article 39 of the Pharmaceutical Industry Code of Good Practices.

2. Events

Informational, promotional and scientific meetings, meetings for specific professionals, congresses, conferences, symposia and similar events, including but not limited to meetings of advisory bodies, visits to research institutes and manufacturing plants, meetings of researchers, meetings dedicated to planning, training and other issues relating to clinical trials and/or non interventional studies

- as defined under Article 26 of the Pharmaceutical Industry Code of Good Practices, organised or sponsored by a Signatory of the Transparency Code, on its behalf or at its request.

3. Healthcare organisation

Any entity:

(a) which is a healthcare centre, medical organisation or scientific organisation operating in the area of health and/or medicine, irrespective of its organisational or legal form, such as a hospital, clinic, foundation, university, other teaching institution or scientific society (except for patients organisations as defined by the Pharmaceutical Industry Code of Good Practices), or

(b) through which one or more healthcare professionals provide services,

- having its registered office in Europe.

Healthcare organisations do not include entrepreneurs engaged in the wholesale or retail trade of medicinal products.

4. Healthcare professional

Any natural person:

(a) who is a physician, dentist, pharmacist, physician assistant (senior physician assistant), nurse, obstetrician, medical laboratory scientist, paramedic or pharmacy technician; or

(b) other than the persons listed in (a) above, who, due to his/her profession, is entitled to prescribe, purchase, supply, recommend or administer medicinal products; or

(c) who is an official or employee of a government agency or other organisation or institution (whether in the public or private sector) which may purchase, supply or administer medicinal products, if such a person participates in the process of purchasing, supplying or administering medicinal products,

- who pursues his/her profession in Europe.

Healthcare professionals also include individuals employed by a Signatory of the Transparency Code under a contract of employment or other civil-law contract, whose main responsibility is pursuing professions listed in items (a) or (b) above.

5. Pharmaceutical Industry Code of Good Practices

The Pharmaceutical Industry Code of Good Practices adopted by the INFARMA Employers' Union of Innovative Pharmaceutical Companies on 24 June 2008, as amended.

6. Medicinal product

Medicinal product for human use as defined under Article 2(32) of the Pharmaceutical Law of 6 September 2001, Journal of Laws of 2008, No 45, item 271, as amended.

7. Signatory of the Transparency Code

a) Member of INFARMA,

b) other entities,

- which acceded to the Transparency Code under Article 20 of the Transparency Code.

8. Beneficiary

Any Healthcare professional or Healthcare organisation receiving Transfers of Value and residing or having its registered office in Europe.

9. Transfers of Value relating to Research and Development

Transfers of Value to Healthcare professionals or Healthcare organisations relating to planning or conducting (i) non-clinical trials (as defined in the OECD Principles of Good Laboratory Practice), (ii) clinical trials (as defined in the Pharmaceutical Law of 6 September 2001, Journal of Laws of 2008, No 45, item 271, as amended) or (iii) non-interventional studies (Chapter V of the Pharmaceutical Industry Code of Good Practices).

10. Transfers of Value

Funds, benefits in kind and other benefits (including compensation for services) transferred by Signatories of the Transparency Code, directly or indirectly, to Healthcare professionals or Healthcare organisations. A direct Transfer of Value shall be understood as a Transfer of Value made directly by a Signatory of the Transparency Code for the benefit of a Beneficiary. An indirect Transfer of Value shall be understood as a Transfer of Value made for the benefit of a Beneficiary by a third party, but on behalf of or at the request of a Signatory of the Transparency Code, if the enterprise of the Signatory of the Transparency Code is known to or can be easily identified by the Beneficiary.

11. Transparency Code

The Transparency Code of the INFARMA Employers' Union of Innovative Pharmaceutical Companies.

12. Reporting period

The full calendar year in which the Beneficiary received Transfers of Value.

13. Standardised template

The standardised template in the form set out in Appendix 1 to the Transparency Code.

Article 3

Subjective scope of the Transparency Code

1. The provisions of the Transparency Code are binding upon a Signatory of the Transparency Code from the date of the Signatory's accession to the Transparency Code, under Article 20(2) of the Transparency Code.
2. Other entities may apply the provisions of the Transparency Code as a set of principles. Respecting them voluntarily ensures compliance with high ethical operational standards.

Article 4

Precedence of law

1. The applicable laws governing the issues regulated by this Transparency Code shall have precedence over the provisions of the Transparency Code.
2. Should the applicable law envisage equivalent or stricter reporting requirements with respect to information about cooperation and related Transfers of Value, Signatories of the Transparency Code undertake to meet all those requirements as much in accordance with the provisions of the Transparency Code as possible. Should the applicable law envisage reporting requirements with respect to cooperation and related Transfers of Value which are less stringent than the provisions of the Transparency Code, this shall not preclude the obligation of Signatories to apply the provisions of the Transparency Code.
3. If the fulfilment of obligations under the Transparency Code results in the violation of the applicable law, the failure to fulfil those obligations shall not be regarded as an infringement of the provisions of the Transparency Code.

CHAPTER II

REQUIREMENTS FOR DISCLOSURES REGARDING COOPERATION AND RELATED TRANSFERS OF VALUE

Article 5

General obligation

1. Each Signatory of the Transparency Code shall document and disclose Transfers of Value it makes, directly or indirectly, to or for the benefit of a Beneficiary, in accordance with the rules set out in this Chapter.
2. The following Transfers of Value do not fall within the scope of the disclosure obligation referred to in Section 1 above:
   (a) transfers which are solely related to non-prescription medicines,
   (b) materials and objects referred to in Article 38(2) and (3) of the Pharmaceutical Industry Code of Good Practices,
   (c) meals referred to in Article 27 of the Pharmaceutical Industry Code of Good Practices,
   (d) samples referred to in Article 22 of the Pharmaceutical Industry Code of Good Practices,
   (e) discounts, rebates and other trading mechanisms generally applied in the sale of medicinal products by Signatories of the Transparency Code to Healthcare professionals or Healthcare organisations.

Article 6

Reporting methods

1. Each Signatory of the Transparency Code shall disclose information about cooperation and related Transfers of Value to Healthcare professionals and Healthcare organisations within 6 months of the end of the relevant reporting period. A reporting period shall each time cover a full previous calendar year ("Reporting Period").
2. A disclosure consists in the publication of the standardised template in the form set out in Appendix 1 to the Transparency Code ("Standardised Template"), filled out in Polish, on the website of a Signatory of the Transparency Code. At the end of the Standardised Template, Signatories of the Transparency Code describe in detail their methodology, in particular the method of assigning Transfers of Value to Beneficiaries, the treatment of multi-year contracts, tax issues, currency issues and any other issues relating to dates and amounts. The Transfers of Value shall be disclosed in Polish zlotys (PLN). The Standardised Template shall include total Transfers of Value to Beneficiaries from the Signatory of the Transparency Code and from companies of the Signatory's capital group, taking into account the principles specified in Article 13 of the Transparency Code.
3. Each Signatory of the Transparency Code shall ensure that the information disclosed in accordance with this Article remains in the public domain for the period of 3 years following the time such information was first disclosed, unless the Recipient's consent to the disclosure of Transfers of Value has been revoked.

   For Recipients being natural persons, each Signatory of the Transparency Code shall ensure that the information is disclosed without prejudice to the Beneficiary's right to protection of their personal data. In particular, to this end each Signatory of the Transparency Code shall obtain all the necessary permissions required by the applicable laws, including the Personal Data Protection Act of 29 August 1997 (Journal of Laws of 2002, No 101, item 926, as amended). Each Signatory of the Transparency Code undertakes to make the necessary efforts to obtain the relevant approvals, taking into account the objective referred to in the Preamble to the Transparency Code.

Article 7

Documentation and record-keeping

Each Signatory of the Transparency Code shall document all Transfers of Value subject to the disclosure obligation in accordance with the Transparency Code, and keep the relevant documents for at least 5 years from the end of the relevant Reporting Period.

Article 8

Transfers of Value to Healthcare professionals

1. Subject to Article 5(2) of the Transparency Code, Transfers of Value made by a Signatory of the Transparency Code to Healthcare professionals from any of the categories listed below shall be disclosed:

   (a) Expenses incurred in relation to the Events referred to in Article 2(2) of the Transparency Code.

   Expenses incurred in relation to the Events are presented as:

   (i) registration fees,

   (ii) travel and accommodation.

   (b) Compensation for any services provided by a Healthcare professional for the benefit of a Signatory of the Transparency Code or third parties, but at the request of the Signatory of the Transparency Code.

   Compensation for services shall be presented as:

   (i) remuneration,

   (ii) additional expenses reimbursed or incurred for the benefit of a Healthcare professional by a Signatory of the Transparency Code under an agreement.

   (c) Transfers of Value relating to Research and Development, subject to Article 11(3) of the Transparency Code.

   (d) Other than expenses from the aforementioned categories.

Article 9

Transfers of Value to Healthcare organisations

1. Subject to Article 5(2) of the Transparency Code, Transfers of Value to Healthcare organisations made by a Signatory of the Transparency Code from any of the categories listed below shall be disclosed:

   (a) Donations as defined in Article 2(1) of the Transparency Code.

   (b) Expenses incurred in relation to the Events referred to in Article 2(2) of the Transparency Code.

   Expenses incurred in relation to the Events are presented as:

   (i) registration fees,

   (ii) travel and accommodation,

   (iii) value of sponsorship agreements concluded with Healthcare organisations or third parties (including providers of commercial services) to organise an Event.

   (c) Compensation for any services provided by Healthcare organisations for the benefit of a Signatory of the Transparency Code or third parties, but at the request of the Signatory of the Transparency Code.

   Compensation for services shall be presented as:

   (i) remuneration,

   (ii) additional expenses reimbursed or incurred for the benefit of a Healthcare organisation by a Signatory of the Transparency Code under an agreement.

(d) Transfers of Value relating to Research and Development, subject to Article 11(3) of the Transparency Code.

(e) Other than expenses from the aforementioned categories.

Article 10

Requirements for individual disclosure

1. Unless otherwise stated herein, and without prejudice to the applicable laws and the Beneficiary's right to protection of his/her personal data, Transfers of Value shall be disclosed by assigning to each identifiable Beneficiary an amount corresponding to the Transfer of Value made to that Recipient in the relevant Reporting Period (hereinafter: "individual disclosure").
2. Transfers of Value made to a Beneficiary shall be disclosed under the categories set out in Articles 8 and 9 of the Transparency Code. Whenever so required by a Beneficiary or authorities entitled to request the disclosure of such information under the applicable law, a Signatory of the Transparency Code shall submit a detailed specification of all Transfers of Value under the relevant category to the requesting entity.
3. Each Signatory of the Transparency Code shall ensure that upon request of a Beneficiary, data regarding the Recipient is supplemented, updated, corrected or deleted immediately (no later than 14 days after the Recipient made the request), if such data is incomplete, outdated, untrue or if such data has been collected in infringement of the Beneficiary's rights.

Article 11

Requirements for aggregate disclosure

1. If, due to the applicable provisions of law, information about Transfers of Value received by a Beneficiary cannot be disclosed on an individual basis in accordance with Article 10(1) of the Transparency Code, a Signatory of the Transparency Code shall disclose the amounts corresponding to all Transfers of Value made to that Recipient in the relevant Reporting Period.
2. For each Transfer of Value category, the aggregate disclosure referred to in Section 1 of this Article shall specify:
   (a) the number of Beneficiaries concerned, expressed in figures and as a percentage of all Recipients who received Transfers of Value from a Signatory of the Transparency Code in the relevant Reporting Period; and
   (b) the total amount corresponding to the Transfers of Value made to those Recipients.
3. Transfers of Value relating to Research and Development shall be disclosed by a Signatory of the Transparency Code by disclosing a single amount: the sum of all Transfers of Value under that category made to all Recipients in the relevant Reporting Period.

Article 12

Non-duplication

Where a Transfer of Value is obtained by a specific Healthcare professional through a Healthcare organisation, that Transfer of Value shall be disclosed only once. To the extent possible, such disclosure should be made as a disclosure regarding Transfers of Value received by a Healthcare professional under Article 8 of the Transparency Code.

Article 13

Requirements for disclosures regarding cross-border Transfers of Value

1. Where a Recipient has a place of residence or registered office outside the territory of Poland, a Signatory of the Transparency Code shall ensure that the disclosure is made by a company from the capital group of the Signatory having its registered office in the country of residence or registered office of the Beneficiary, in accordance with the code of the relevant EFPIA Member organisation being in force in the country where the Recipient has its place of residence or registered office. Where a Signatory of the Transparency Code has no affiliated undertaking in that country, that Signatory shall make the disclosure in accordance with the provisions hereof.
2. If the Beneficiary has its place of residence or registered office in Poland, and the Transfer of Value is made to this Beneficiary by a company from the capital group of the Signatory of the Code with its registered office outside Poland, the disclosure shall be made by the Signatory of the Code in accordance with this Transparency Code in the Standardised Template referred to in Article 6(2) of the Transparency Code.

Chapter III

SANCTIONS IN RELATION TO SIGNATORIES OF THE TRANSPARENCY CODE

Article 14

Disciplinary Court

Any disputes which may arise in connection with the Transparency Code, or cases of infringement of the provisions thereof shall be settled by the Disciplinary Court ("Disciplinary Court") operating at INFARMA, in accordance with the Statute of INFARMA as well as the Rules of Procedure of the Court.

Article 15

Primary objective of the Disciplinary Court

The primary objective of the Disciplinary Court is not to issue decisions regarding a fault of a Signatory of the Transparency Code, but to settle potential disputes in the general public interest.

Article 16

Entities entitled to lodge a complaint

The following entities are entitled to lodge a complaint with the Disciplinary Court in matters set forth in this Transparency Code:

(a) Signatory of the Transparency Code;

(b) Member of INFARMA;

(c) other entities, through the Management Board of INFARMA.

Article 17

Scope of examination

1. Cases in which proceedings have been commenced before state administration authorities or courts of law shall be excluded from the jurisdiction of the Disciplinary Court.
2. In the case of infringement of the applicable law and the provisions of the Transparency Code, the Disciplinary Court shall examine the case only to the extent of a potential infringement of the provisions of the Transparency Code.

Article 18

Sanctions

1. If a delay in the disclosure or a failure to disclose information required under the Transparency Code is found, the Disciplinary Court may, taking into account the period and reasons of the delay or failure, as well as any previous infringement (if any) of the provisions of the Transparency Code, impose on a Signatory of the Transparency Code the penalties provided for in the Statute of INFARMA and the Pharmaceutical Industry Code of Good Practices in its version valid as of the date of the Court's decision.

Article 19

Publication of decisions of the Disciplinary Court

1. Each final decision of the Disciplinary Court regarding the application of the Transparency Code shall be published in the INFARMA Bulletin.
2. In the case of serious or repeated infringements, the publication shall indicate the business name of the Signatory of the Transparency Code and the details of the case. In the case of minor infringements, or where no infringement was found, the publication need not indicate the business name of the Signatory of the Transparency Code.

In each case, the exact content of the published information concerning the decision shall be decided by the Court in the conclusion of the decision. In particular, the educational purpose of such publication shall be taken into account.

Chapter IV

IMPLEMENTING PROVISIONS

Article 20

Accession to the Transparency Code

1. The Transparency Code is open for accession to all entrepreneurs from the pharmaceutical industry.
2. Accession to the Transparency Code requires submission of a written statement to the Management Board of INFARMA in the form set out in Appendix 2 to the Transparency Code.
3. The Signatory of the Transparency Code undertakes to ensure that companies from its capital group will apply the provisions of this Transparency Code, in particular by providing it with information about Transfers of Value made by these companies to the Beneficiaries having their place of residence or registered office in Poland in order for this information to be included in the Standardised Template.

Article 21

Termination of the Transparency Code

Each Signatory may terminate the Transparency Code with 30 days' notice by submitting a written statement to the Management Board of INFARMA.

Article 22

Amendments to the provisions of the Transparency Code

1. Amendments to the Transparency Code shall be accepted by the simple majority of voting Signatories of the Transparency Code.
2. Proposals of amendments to the Transparency Code may be submitted by Signatories of the Transparency Code, the Management Board of INFARMA or the Disciplinary Court.
3. Proposals shall be immediately communicated to all Signatories of the Transparency Code for approval or rejection. A Signatory's failure to communicate its opinion within one month of the date of receiving the aforementioned proposal shall be equivalent to acceptance of the amendment to the Transparency Code without any objections.
4. INFARMA shall inform all Signatories of the Transparency Code of received opinions, as well as approval or rejection of amendments, no later than within one month of the expiration of the consultation date referred to in Section 3.
5. Amendments approved in line with this Article shall enter into force on the date stipulated in the notice referred to in Section 4, yet no sooner than 45 days of the date of dispatch of the notice.

Article 23

Miscellaneous

1. Appendices to the Transparency Code form an integral part hereof.
2. The calendar year 2015 shall be the first Reporting Period.

Appendix 1

STANDARDISED TEMPLATE

1. Transfers of Value received by Healthcare professionals

TRANSFERS OF VALUE MADE BY *[name of the entity]* **and companies from its capital group with registered office outside Poland**							
First name and surname	Full address of the main place of business	Professional Code (optional)	Expenses incurred in relation to the Events		Compensation for services		Total
			Registration fees	Travel and accommodation	Basic remuneration	Additional expenses	
INDIVIDUAL DISCLOSURE							
AGGREGATE DISCLOSURE							
Total Transfers of Value received by Beneficiaries							
Number of Beneficiaries covered by the aggregate disclosure							
Percentage of Beneficiaries covered by the aggregate disclosure							Not applicable

DESCRIPTION OF THE METHODOLOGY APPLIED: [***]

2. Transfers of Value received by healthcare Organisations

TRANSFERS OF VALUE MADE BY *[name of the entity]* **and companies from its capital group with registered office outside Poland**								
Name	Full address of the main place of business	Donations	Expenses incurred in relation to the Events			Compensation for services		Total
			Registration fees	Travel and accommo-dation	Value of sponsorship agreements	Basic remuneration	Additional expenses	
INDIVIDUAL DISCLOSURE								
AGGREGATE DISCLOSURE								
Total Transfers of Value received by Beneficiaries								
Number of Beneficiaries covered by the aggregate disclosure								
Percentage of Beneficiaries covered by the aggregate disclosure								Not applicable

DESCRIPTION OF THE METHODOLOGY APPLIED: [***]

3. Transfers of Value relating to Research and Development

- total: [***]

SIGNATORIES OF THE TRANSPARENCY CODE

1. ABBOTT LABORATORIES Poland Sp. z o.o.
2. ABBVIE Polska Sp. z o.o.
3. ACTELION Pharma Polska Sp. z o.o.
4. ALCON POLSKA Sp. z o.o.
5. ALLERGAN Sp. z o.o.
6. AMGEN BIOTECHNOLOGIA Sp. z o.o.
7. ASTELLAS PHARMA Sp. z o.o.
8. ASTRAZENECA PHARMA POLAND Sp. z o.o.
9. BAXTER POLSKA Sp. z o.o.
10. BAYER Sp. z o.o.
11. BIOGEN IDEC POLAND Sp. z o.o.
12. BOEHRINGER INGELHEIM MARKETING Sp. z o.o.
13. BRISTOL – MYERS SQUIBB POLSKA Sp. z o.o.
14. CELGENE Sp. z o.o.
15. CHIESI POLAND Sp. z o.o.
16. ELI LILLY POLSKA Sp. z o.o.
17. GSK COMMERCIAL Sp. z o.o.
18. IPSEN POLAND Sp. z o.o.
19. JANSSEN-CILAG POLSKA Sp. z o.o.
20. LUNDBECK POLAND Sp. z o.o.
21. MERCK Sp. z o.o.
22. MSD POLSKA Sp. z o.o.
23. NOVARTIS POLAND Sp. z o.o.
24. NOVO NORDISK PHARMA Sp. z o.o.
25. PFIZER POLSKA Sp. z o.o.
26. PIERRE FABRE MEDICAMENT POLSKA Sp. z o.o.
27. SANOFI-AVENTIS Sp. z o.o.
28. SANOFI PASTEUR Sp. z o.o.
29. ROCHE POLSKA Sp. z o.o.
30. TAKEDA Polska Sp. z o.o.
31. UCB PHARMA Sp. z o.o.


MEDICAL
MEDICAL
Health Care
Doctor
Hospital
Pharmacist
Nurse
Dentist
First Aid
Surgeon
Emergency

INFARMA
Employers' Union of Innovative
Pharmaceutical Companies

Puławska 182 Str.
02-670 Warsaw
Poland

biuro@infarma.pl
www.kodeksprzejrzystosci.pl

T. +48 22 417 01 70
F. +48 22 468 87 05

3rd Edition