



Disclosure

INTRODUCTION



Management of the Czech Medical Association of J. E. Purkyně (CzMA) considers the initiative Transparent cooperation as a step in the right direction. Collaboration of physicians with the pharmaceutical industry is essential and the efforts of the Association of Innovative Pharmaceutical Industry (AIFP) to share information about this cooperation through their websites and many other materials is necessary. The public wants to be informed about the relationships that affect the management of public funds, and there is no doubt that the initiative Transparent cooperation brings needed change in this field.

The form that AIFP decided for during disclosure of information is considered by the CzMA to be adequate and appropriate to the situation in developed European countries in which implementation of the principles of the Transparent cooperation initiative was performed without major problems.

As a crucial fact in this regard considered by the CzMA is that during implementation of the Transparent cooperation initiative a refusal of disclosure of the information is allowed in accordance with the rules for personal data protection of the respective legal provisions. Similar transparency of relations is not yet common in other fields or occupations. The CzMA respects and supports implementation of the Transparent cooperation initiative also in the Czech Republic.

A handwritten signature in blue ink, appearing to read 'Štěpán Svačina'.

Prof. Dr. Štěpán Svačina, DrSc., MBA
Chairman of the CzMA



„Cooperation of the best healthcare professionals or institutions with the pharmaceutical companies is an essential part of the healthcare system. It has a positive effect on the quality of provided care and its continuous improving.“

Last year the innovative pharmaceutical industry placed 37 medicines with a brand new active substance on the market.

Without intensive cooperation between the pharmaceutical industry and healthcare professionals these innovations would not exist.

The Europe-wide initiative Transparent cooperation is a self-regulating project of the pharmaceutical companies that will contribute to transparency and clarification of the principles of cooperation between healthcare professionals and pharmaceutical companies.

Continuing education of physicians is a part of cooperation with industry“, says Jakub Dvořáček. Industry is one of the guarantor of high professional expertise of the physicians who patients trust. „This cooperation is essential because nobody can inform about a medicine and its effects better than the manufacturer.“ In this area particularly high ethical standards are valid already today.

A handwritten signature in blue ink, which appears to be 'Jakub Dvořáček', written in a cursive style.

Mgr. Jakub Dvořáček

Executive Director of AIFP



The Ministry of Health of the Czech Republic supports the initiative Transparent cooperation and considers it as one of the most important steps leading to the real cultivation of the state of the Czech healthcare system.

This initiative is ultimately a follow up of the amendment of the public health insurance, so called transparency amendment that would increase efficiency and transparency of the contractual relations and financial flows in the public health insurance system, and will have undoubtedly a significant impact on the quality of provided health services. A part of the so-called Transparency amendment is the obligation to disclose the contractual documents, without exception and so far

unprecedentedly, which are closed between the health insurance companies and medical service providers as well as distributors of medicinal products.

The Ministry of Health of the Czech Republic has managed to carry through the Transparency amendment as one of the key elements in its long-term endeavour to ensure the effectiveness of spending the public funds for health services. This is a major aspect of the fight against corruption which allows public control of the contracts which establish and regulate major financial transfers of funds from the public health insurance.

The public must be regularly informed about the management with public funds and in this regard the Ministry of Health of the Czech Republic considers the pan-European initiative Transparent cooperation de facto as a positive and needed element in the European healthcare system that brings more light on the payments in the health care system and thereby prevents its misuse for the purposes which could lead to incorrect practices in providing health care. Even through this step the efforts to achieve the highest quality in health care are supported. The Ministry of Health cannot but support this activity and thank its organizers for having the forces to do this plan.

A handwritten signature in blue ink, appearing to read 'Lenka Teska Arnoštová'.

JUDr. Lenka Teska Arnoštová, Ph.D.
Deputy of the Ministry of Health
of the Czech Republic



MINISTERSTVO ZDRAVOTNICTVÍ
ČESKÉ REPUBLIKY

Svatopluk NĚMEČEK
ministr

V Praze dne 20. října 2014
Č.j.: MZDR 52595/2014-2/MIN/KAN



MZDRX00NNLYP

Vážený pane řediteli,

v návaznosti na Váš dopis ze dne 7. října 2014, v němž mne informujete o projektu Asociace inovativního farmaceutického průmyslu (AIFP) založeném na celoevropské iniciativě týkající se zveřejňování plateb nebo jiných plnění mezi farmaceutickým průmyslem a zdravotnickými odborníky a zařízeními pod názvem „Transparentní spolupráce“ a současně žádáte o převzetí záštity nad tímto projektem, Vám sděluji, že mi bude ctí převzít osobní záštitu nad uvedenou aktivitou.

Přeji Vám i dalším členům AIFP, aby první zveřejnění dat za rok 2015, které proběhne v roce 2016, významně přispělo ke kultivaci českého zdravotnictví.

S pozdravem

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INTRODUCTION

The Czech Medical Association of Jan Evangelista Purkyně (CzMA JEP) groups together the specialists and other workers in the healthcare system and related fields in order to develop and extend scientifically based knowledge of medical sciences and related fields. It is involved in increasing of the level of professional knowledge of its members and supports the scientific and research activity in the healthcare system while ensuring strict compliance with ethical principles of the healthcare profession.

In the Czech Republic the Association of Innovative Pharmaceutical Industry (AIFP) associates 31 pharmaceutical companies with its own research and development of medicinal products. Among other things, it binds its members with strict self-regulating rules in the area of ethics which are often beyond the level required by law. AIFP strives to extend the ethical principles to the pharmaceutical companies outside the association, strengthening the standards of cooperation with professional medical public and following general ethical principles in all aspects of the Czech healthcare system.

There has been a long-term cooperation between the CzMA of JEP and AIFP in the area of ethics. Already in 2008, both sides signed a joint declaration unifying the rules of mutual communication and cooperation, and since that time they strive for ensuring and

adherence with these rules so as the mutual relations were based on the acceptance of high ethical standards while respecting patient rights and expectations of society, and especially preservation of independence of both parties in their activities. Therefore, the mutual cooperation in the field of information about the products and promotion of the registered medicinal products, expert meetings organized or sponsored by pharmaceutical industry, clinical research and advisory services was transparently regulated in their joint declaration. In 2013, both parties undertook to provide information on possible conflict of interest by means of so called Disclaimer, i.e. a declaration by which the author openly declares his/her contractual obligations to the pharmaceutical companies in the past year (consultation activities, cooperation in a clinical trial, participation in professional congresses, etc.) which are directly related to the published topic.

The public requirements for transparency of mutual relationships in the pharmaceutical industry and professionals are increasing. Therefore, pharmaceutical industry made another step and informed the public about all financial and non-financial transfers of value between the pharmaceutical companies and healthcare professionals and organizations.

INTRODUCTION OF THE PROJECT DISCLOSURE

Cooperation between healthcare professionals or organizations and pharmaceutical companies is an integral and essential part of a modern healthcare system. Mutual relations have a fundamental and positive impact on providing health care and quality of medical research and therefore it is absolutely essential for successful and rapid development of new medicinal products.

Despite this we are witnessing daily the pressure of the public, media and politicians to make these relations more transparent, to clarify them and to establish clear rules these relations are to follow to ensure that prescription of the medicinal products and professional level of such cooperation shall be governed exclusively by the interest of the patient.

There is a worldwide discussion how should mutual relationships between the pharmaceutical industry and professionals look like and how to contribute to enhance trust of the professional and lay public in cooperation between these subjects. Some states which took specific steps - the United States of America adopted a law regulating information for public regarding all financial and non-financial transactions between the pharmaceutical companies and healthcare professionals and organizations (The Sunshine Act). In Europe the similar laws were implemented in the United Kingdom (The UK Bribery Act) and France (The Loi Bertrand Act).

In addition to state-controlled regulation the self-regulating initiatives of the pharmaceutical companies are in progress.

The information on transfers of value provided by the pharmaceutical industry to the healthcare professionals is provided for example by the Dutch self-regulating platform CRG. In June 2013, the European Federation of Pharmaceutical Industries and Associations (EFPIA) associating the pharmaceutical companies with own research and development of medicinal products and their national associations adopted the Code regulating disclosure of payments as well as other transfers of value from the pharmaceutical companies to the healthcare professionals and organizations. The aim of this transparent initiative is to clarify rationale and extent of cooperation between the professionals and pharmaceutical industry and disclose the level of the related transfers of value. The EFPIA code was implemented by all national associations associated in EFPIA on January 1, 2014.

AIFP which associates innovative pharmaceutical companies in the Czech Republic also implemented this Code that became binding for all its members. Also the non-member companies voluntarily join the project Disclosure. It is therefore clear that the healthcare professionals and organizations will meet more often with the requirement of the pharmaceutical industry to disclose the provided transfers of value. The purpose of this publication is to introduce the project Disclosure, getting it closer to professional public and explaining the frequently asked questions and uncertainties which appear in relation to disclosure of information on provided transfers of value in practice.

HOW WILL THE DISCLOSURE PROCEED

To whom the disclosure obligation applies

Information on performed payments and other transfers of value must be disclosed by the pharmaceutical companies associated in AIFP and by those companies which voluntarily joined to the project Disclosure. The payments and other transfers of value provided to the healthcare professionals and organizations with the main place of practice in the Czech Republic shall be disclosed.

A healthcare professional is a physician or pharmacist. A healthcare organization

is any legal person (i) that is a healthcare, medical or scientific institution, association or organisation (irrespective of the legal or organisational form) such as hospitals, clinics, professional associations, foundations, universities or other teaching institutions or (ii) through which one or more healthcare professionals provide their services. A healthcare organization is also the company or other legal entity established by another healthcare professional who may also be its employee.

What information shall be disclosed

All payments and other transfers of value provided to the healthcare professionals and organizations by the pharmaceutical companies associated in AIFP or by those companies which voluntarily joined the project Disclosure will be disclosed in relation to development, research and sale of the medicinal products for human use under medical prescription (Rx products).

The transfers of value related to donations, grants, sponsoring of professional events, remuneration for services and consultations as well as the information on transfers of value in the science and research in relation to the Rx products shall be disclosed. It does not have to be only the financial transfers of value but also the value in kind shall be disclosed (see next).

What information is not subject to disclosure

The obligation of disclosure does not apply to the information on transfers of value that is related solely to over the counter medicinal products, payment related to common purchases and sale of pharmaceuticals

(purchase prices, discounts, rabats, etc.), and educational materials, samples and hospitality which are subject to special rules and limitations specified in the Ethics code of AIFP.

Where the information will be disclosed

In the Czech Republic the payments and other transfers of value between the professionals and pharmaceutical industry are available on the portal www.transparentnispoluprace.cz.

Meanwhile, the disclosure is performed in the country where the recipient is based in (a healthcare organization) or where it has

its main practice (a healthcare professional). Even if a Czech professional is sponsored from a foreign pharmaceutical company, e.g. for a lecture in abroad, the disclosure shall be performed at the place of his/her main practice, i.e. in the Czech Republic and in accordance with the principles of the project Disclosure.

How will the information be disclosed?

The total annual sum for all payments and other transfers of value related to the activities of cooperation in the respective category shall be disclosed.

The information on transfers of value will be disclosed at an individual level, i.e. including information about the payer, i.e. a particular pharmaceutical company, and the recipient, i.e. a healthcare professional or organization. Identification of the healthcare professional will be performed based on his/her first name, surname, address of his/her main practice and the registration number in the Czech Medical Association or Czech Pharmacy Association.

Identification of the healthcare organization will be performed based on the name, address and ID. Other private information of the recipients (e.g. ID, address, etc.) shall not be disclosed.

Some information will be subject to collective disclosure. In these transfers of value the data on a payer will be included but not about a particular recipient; only a cumulative amount for all such payments, number of recipients included in this cumulatively documented amount and a percentage of such recipients from the total number of recipients for a respective payer shall be stated.

How will it be possible to find information and how they will be displayed?

The portal www.transparentnispoluprace.cz will be divided into the internal section and public section.

The public section enables search by the name of a healthcare professional, address of his/her practice and the registration number assigned by the Czech Medical Association or Czech Pharmacy Association that can be found in the database of professionals on www.clk.cz or www.lekarnici.cz. As for a healthcare organization the search will be performed based on its name, address, or ID, if provided.

Only one healthcare professional or organization is displayed for the searching person. The total annual amount in the respective category of cooperation with the name of the pharmaceutical company that provided payment shall be displayed.

The data that will be disclosed collectively, i.e. without identification data of the recipient according to the rules of the project Disclosure can be found after entering the name and ID of the pharmaceutical company which provided transfers of value.

In order to prevent misuse of the data in this database it will not be possible to display data of more healthcare professionals or organizations at once. It will not be possible to modify or download data and the web page will be protected with the security features.

The internal part enables secure access for the pharmaceutical companies involved in the project only to their own data. The

administrator access will be provided exclusively for a limited number of employees of AIFP. It will not be possible to edit data, the pharmaceutical company that entered the data will be responsible for it and the database will comply with the requirements of personal data protection. The professional or a deputy of the healthcare organization will be able to verify the data before disclosure.

When and for how long the information will be disclosed

Information will be disclosed annually (the reporting period corresponds to one calendar year) and will be publically available 6 months after the end of the displayed period

for at least 3 years from disclosure. The first reporting period will be 2015 and the disclosure will be made by June 30, 2016.

PAYMENTS AND OTHER TRANSFERS OF VALUE PROVIDED TO SINGLE HEALTHCARE PROFESSIONALS

Cooperation between a pharmaceutical company and a professional that is subject to disclosure obligation under the rules of the project Disclosure can be divided into the following categories.

Contributions to the costs of events

This category does not include registration fees and the costs for transport and accommodation. It includes the costs for participation of the professionals at the congresses and similar educational events organized or sponsored by pharmaceutical industry.

In the subcategory transport and accommodation all expenses such as costs for air tickets, tickets, fleet of cars, toll fare, parking fees, taxi and accommodation in

the hotels must be disclosed. In some cases the Code does not require the payments or other transfers of value be divided to a group of healthcare professionals. For example, if public transport is ensured for a group (e.g. bus) to an event these expenses can be disclosed collectively and they do not need to be prorated to single healthcare professionals.

The data in this section should be disclosed individually, i.e. with identification data of the healthcare professional.

It should be noted that the expenses for hospitality are not included in this or other category that is subject to disclosure;

hospitality is subject to special ethical rules and it is regulated separately (for more information see www.aifp.cz).

Reimbursement of services and consultations

Within this category especially the payments to speakers, trainings for speakers, transfers of value for expert articles, data analysis, preparing of educational materials and general consultations shall be disclosed.

Participation of a healthcare professional at market research shall be disclosed in this category on condition that the member

company knows his/her identity (the market research is usually performed anonymously and the pharmaceutical company does not know identity of the single participants).

The data in this section should be disclosed individually.

Transfers of value associated with research and development

The single healthcare professionals regularly take part in research and development of the medicinal products under prescription performed by the pharmaceutical companies. They collaborate in the clinical and non-clinical trials and non-interventional post-registration studies. Also the expenses associated with the events related to research and development shall be published in this category.

The data in this section are disclosed collectively, i.e. without identification data

of the concerned professional. Exceptions include the payments or other transfers of value related to the retrospective non-interventional studies which will be disclosed under the name of an individual recipient in the category remuneration for services and consultation. On the contrary, the interventional studies which are prospective in nature will be included in the collective disclosure of payments or other transfers of value within the category of research and development.

PAYMENTS AND OTHER TRANSFERS OF VALUE PROVIDED TO THE HEALTH-CARE ORGANIZATIONS

Cooperation between a pharmaceutical company and a healthcare organization that is subject to disclosure obligation under the rules of the project Disclosure can be divided into the following categories.

Gifts and grants

Disclosure of the donations and grants should be made individually for a legal entity that is a recipient of the payment or other transfers of value - it can be a hospital or university but also a separate department (if it has a legal status).

This includes also providing of a charitable donation to a healthcare organization. Humanitarian aid is material and logistic help

to people in need and the member companies could be asked this way to provide medicines; if a charitable donation of products is made in this regard such transfers of value shall be disclosed in the category „donations and grants“.

The data in this section should be disclosed individually, i.e. with identification data of the healthcare organization.

Contributions to the costs of events

Within this category the registration fees, costs of transport and accommodation and contracts on sponsoring which are closed either directly with a healthcare organizations or with a third party that was authorized by a healthcare organization to organize an event shall be disclosed.

The subcategory of contracts on sponsoring include especially the rent of exhibition

stands or advertising space (a paper banner, electronic or other format), satellite symposium at a congress, sponsoring of speakers, drinks or refreshment (if it is a part of the package) provided by the organizers, courses ensured by a healthcare organization, etc.

The transfers of value in this section shall be disclosed individually.

Reimbursement of services and consultations

Similar rules as for the same category in a healthcare professional apply for this category. Payments to speakers, speakers' training, transfers of value for medical articles, data analysis, educational materials and general consultation services paid to

a healthcare organization shall therefore be disclosed.

The data in this section shall be disclosed individually.

Transfer of value associated with research and development

Not only the single healthcare professionals but also the healthcare organizations are often involved in cooperation in clinical trials, non-clinical trials and non-interventional studies. Payments and other transfers of value related

to their participation are subject to collective disclosure except for the retrospective non-interventional studies which are disclosed individually in the category of remuneration for services and consultations.

PROTECTION OF PERSONAL DATA

Ensuring protection of private data of the health-care professionals

When preparing the project Disclosure and during its implementation care was taken to ensure that disclosure of information is performed entirely in compliance with the European and Czech legislation concerning personal data protection. AIFP introduced the project to the Institute for protection of personal data and received its opinion stating that if all duties of the participating subjects we are stating below are followed the project Disclosure complies with the current legal regulation.

Disclosure of information and personal data of the healthcare professionals is subject to processing of personal data in terms of the Act no. 101/2000 Coll. on personal data protection, as amended. Therefore, it is necessary that each pharmaceutical company that sponsors a healthcare professional and has his/her data for disclosure in terms of the project Disclosure shall be registered as an administrator by the Institute for protection of personal data and must announce processing of such data to the Institute. AIFP, as a founder of the database, where the information on provided payments and other transfers of value will be disclosed is in the position of personal data processor. Data flow between

the administrator (pharmaceutical company) and the processor of personal data (AIFP) is covered in the written agreement on processing of personal data.

The condition which is necessary for processing of personal data of the healthcare professionals in the project Disclosure includes obtaining the consent from the healthcare professional with processing of personal data. The alternative of this procedure is closing a written agreement including specific legal provisions.

Therefore in the future, the healthcare professionals will meet with the fact that the contracts closed with the pharmaceutical company e.g. for sponsoring of participation at a scientific congress will include also the consent with processing of personal data for disclosure according to the rules of the project Disclosure that should be signed.

For completeness, it should be added that personal data protection concerns solely physical entities, i.e. healthcare professionals. The healthcare organizations, i.e. legal entities are not subject to personal data protection under the law.

Partial consent with personal data processing

In practice a situation may occur when a healthcare professional provides his/her consent with processing of personal data only for some transfers of value or he/she decides that he/she provides consent in the case of

provided transfers of value from one company but refuses to provide consent for transfers of value from another company. The same applies also for later partial withdrawal of the consent.

The healthcare professional provides partial consent in one contract with a particular pharmaceutical company

In such case, all transfers of value provided to a healthcare professional from the respective company shall be disclosed collectively.

The healthcare professional provides consent with disclosure only for some contracts of a particular pharmaceutical company

Also in this case all transfers of value (i.e. from the contracts in which the professional provided his/her full consent) will be disclosed collectively. In one pharmaceutical company some transfers of value cannot be disclosed individually and the others in a collective amount.

The healthcare professional provides consent with disclosure only to some pharmaceutical companies

Transfers of value provided by the pharmaceutical companies which were given the consent from a healthcare professional should be disclosed individually. The transfers of value provided by the pharmaceutical companies which were not given consent or if the consent was withdrawn (only partial withdrawal) shall be disclosed collectively for each pharmaceutical company.

Withholding or withdrawal of consent with processing of personal data and its consequences

If the mutual cooperation between the pharmaceutical company and healthcare professional is based on the written consent with processing of personal data the consent can be withdrawn later or it does not have to be provided at all before initiation of cooperation. In case of failure to provide consent or withdrawal of the consent the information on provided transfers of value will continue to be disclosed but not on an individual basis including identification of the respective healthcare professional but collectively, i.e. in anonymous form and together with other payments of the same type.

As for other possibilities of mutual cooperation with the healthcare professional who does not provide his/her consent or

withdraws it later it depends on the internal rules of each pharmaceutical company. Some pharmaceutical companies, especially those with headquarters in the countries with legislation that ensures transparency of mutual relationships can waive or limit their cooperation with the professionals who do not provide or withdraw their consent with disclosure. However AIFP believes that the provided transfers of value have a completely legitimate basis and their disclosure has no negative impact on the mutual cooperation. Transparency of mutual relationships is common in the developed European countries and should be considered as a standard, not as an exception.

With regard to the current legislation in the field of competition it must be emphasized

that the member companies do not share procedures or information on which professionals or organizations will or will

not cooperate in the case of providing or not providing consent with disclosure of data in the project Disclosure.

DISCLOSURE IN PRACTICE

In the previous part we outlined which categories of the provided transfers of value shall be disclosed. However, in practice the relationships between the pharmaceutical professionals or organizations and

pharmaceutical companies could not always be clearly classified to a particular category. Therefore we will try to explain on the examples how the disclosures will be made in particular situations.

Sponsoring of health-care professionals through a third party

Sponsoring of participation of the professionals at the expert events via a third party is so specific and it must be discussed in detail separately, and various models of cooperation and the method of disclosure should be explained. It is a situation that is classified by the Disclosure Code as indirect transfers of value.

Primarily, it has to be elucidated who is the real convener of the respective event.

The convener is a person who convenes the event, i.e. the one whose initiative led to organization of the event. The organizer is

a subject who only organizes the event and through whom the transfers of value are done to the final subjects. It is irrelevant whether the contract with the pharmaceutical company is concluded by the organizer or convener but the decisive point is who is the ultimate recipient of the payment. For identification of a convener and organizer it is not decisive who is stated as official convener. It is possible that the subject who is in fact only the organizer will be stated in the invitation card. However, the fact who is responsible for the initiative to organize the event is decisive.

The organizer is not a healthcare organization

In the case that the organizer of the event does not fall under the definition of a healthcare organization and organizes the event on its own initiative, the payments provided by the pharmaceutical company to the involved healthcare professionals and organizations will not be disclosed, either individually or collectively (e.g. a municipality organizes a seminary with a topic of

healthcare). Exception is a situation when the pharmaceutical company requests sponsoring of participation of a particular healthcare professional. In such case it is irrelevant that the organizer does not fall under the definition of a healthcare organization and the provided transfers of value to the requested healthcare professional will be disclosed individually under his/her name.

The organizer is a healthcare organization

If the event is organized by a convener who meets the definition of HCO (e.g. professional society), a third party will request organizing of the event (organizer) and a pharmaceutical industry would provide some payment to organize the event then such payment shall be disclosed by the organizer, i.e. a HCO whose initiative led to the event. In these cases the organizer is only a mediator and all payments provided from the pharmaceutical companies to the organizer shall be disclosed individually under the name of the healthcare organizations as it is the recipient of payments or other transfers of value.

This applies even in the case when the healthcare organization does not receive a part of the payment to its account as all

the resources will be used for organizing of the event by the organizer. The organizer of the event should inform the pharmaceutical company on which healthcare organizations the event is organized for. In the case of more healthcare organizations on the side of the recipient the transfers of value will be divided with the disclosure based on the actually provided parts or pro rata.

Keep in mind that if a pharmaceutical company requires (also verbally) participation of a particular healthcare professional who will eventually receive the payment the part of payment or other transfers of value will be disclosed individually for the requested professionals.

The organizer is a pharmaceutical company

In the case when the organizer organizes the event for a pharmaceutical company the payments will be disclosed for individual recipients who meet the definition of HCP and HCO. Such organizer will always

provide information on the final recipient to the pharmaceutical company also in case that a particular healthcare professional or organization was not requested by the company itself.

Private healthcare organizations and other private companies

In a separate chapter sponsoring of professionals in light of the existence of primary healthcare organizations and other private companies owned by professionals, e.g. private limited companies must also be discussed. The payments provided to such companies, if they fulfil a definition

of a healthcare organization, must be disclosed by the pharmaceutical companies as well. However, it must be clarified when it is disclosed on the level of a healthcare organization and when on the level of individual healthcare professionals.

The company fulfils the features of a healthcare organization

In such case the provided transfers of value shall be disclosed individually on behalf of the respective healthcare organization.

The company does not fulfil the features of a healthcare organization but a healthcare professional is its sole founder.

Such company even though established by one professional is considered as a healthcare organization. Therefore, the provided transfers of value are published individually at the level of the healthcare organization without the name of its owner.

The company does not fulfil the features of a healthcare organization but more persons including healthcare professionals are its founders.

In this case it does not have to be clear whom the transfers of value was intended to in the company. It is not possible to disclose a payment with the name of the company (because it is not a healthcare organization by definition) but the name of a particular recipient - a healthcare professional - must be stated. In this case his/her consent must be obtained or a contract must be closed.

Market research

According to the Disclosure Code the payments or other transfers of value to the companies which perform market research do not need to be disclosed if the identity of the healthcare professionals or organizations taking part in the research is not known.

One of the basic principles of the market research is the right of responders to remain anonymous which is enshrined in the definitions of the market research and in the respective rules worldwide. However, if the member company knows identity of the healthcare professional or organization taking part in the activities defined as market research this information must be disclosed in the category „remuneration for services and consultation“. In such exceptional cases it is expected that the member company ensures consent with disclosure in the contract.

If the healthcare professional participating in market research mentions an undesirable

effect relating to the product of the sponsoring pharmaceutical company that occurred in a particular patient or group of patients the agency conducting market research must provide this information to the safety department of the company also in the case that it had already been done by the healthcare professional. In order the agencies which perform market research fulfil this pharmacovigilance obligation they ask the healthcare professionals if they are willing to give up on confidentiality only for the purpose of reporting the undesirable effects so as the sponsoring company could contact them if additional information is needed. It has nothing to do with the responsibilities provided during the research. Because it is a necessary exception these payments or other transfers of value do not have to be disclosed to follow the pharmaceutical guidelines.

Transfers of value in kind

Not only financial amounts but also transfers of value in kind or other type must be disclosed. In practice it can be a support of medical publications by pharmaceutical industry. This activity is by itself subject to legal regulation or self-regulation codes which the member companies obeyed to. Without prejudice to valid provisions and codes the support of publication from the member companies,

either directly or indirectly, shall be disclosed.

If a member company provides a non-financial remuneration to a healthcare professional for the services, e.g. writing an article, the provided transfers of value must be disclosed as a sum of money and must be included in the category remuneration for services.

Clinical trials

Transfers of value provided in relation to research and development including also clinical trials are disclosed collectively without identification data of the single healthcare professionals or organizations. It applies also to the transfers of value provided to independent investigators. The costs of events related to a clinical trial are also disclosed within this category (e.g. investigator meetings).

It must be emphasized that a clinical research organization is not a healthcare organization.

The organization that performs clinical research is a company that provides support to the companies which produce pharmaceutical, biotechnological and medical products by means of research services performed externally on the basis of an agreement. However, the member companies can provide payments or other transfers of value to the healthcare professionals or organizations via the organizations performing clinical research - such indirect payments fall under the Code and they must be disclosed.

Payments to universities and other educational organizations

In principle, the Code does not modify disclosure of the interactions between pharmaceutical companies and educational institutions (such as the support or involvement in the educational programs). However, if there is such a support for the benefit of the future or current healthcare professionals such payment or other transfers of value must be recognized according to the Code with identification of the recipient which is the educational institution in this case.

If the member companies cooperate with a university or educational institution, provide payments or other transfers of value for their benefit, etc. it must be ensured that any such support and cooperation is properly documented (best in a contract) so as the provisions on consent with individual disclosure of the provided payments or other transfers of value are included).

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