

## **Methodological note: information disclosure of Heel Rus LLC**

### **1. Approach of Heel Rus to Information Disclosure**

**Heel Rus LLC** (hereinafter Heel RUS) is a subdivision of an international company – Biologische Heilmittel Heel GmbH (Germany) – for many years specializing in development and manufacture of medicines from natural ingredients. Heel RUS carries out its products manufacturing in Germany in accordance with international pharmaceutical standards, in particular meeting the standards of Good Manufacturing Practice (GMP). Laboratories and manufacturing sites of the company are certified by reputable regulatory authorities.

Therefore, the purpose of any information disclosure is a desire of Heel RUS to comply with local and international rules in the field of ethics and compliance and other standards of the pharmaceutical industry applied in the field of Health Care of the Russian Federation, and to demonstrate transparent, honest relationship with Health Care Professionals and Organizations based solely on business necessity, development of science and innovations, and improvement of medical treatment for patients.

Interaction of pharmaceutical industry players with Health Care Professionals and Organizations is based on exchange of expert knowledge based both on clinical experience and on experience in diseases treatment, the ultimate goal of which is to take care of patients. Health Care Professionals and Organizations should receive fair compensation for the services they provide to pharmaceutical companies. Heel RUS' goal is to ensure that information on such interaction is collected and published in accordance with all applicable local requirements for transparency. Heel Rus observes high standards of ethics, according to which it shows a firm intolerance to any possible transfer of any values in order to exert undue influence.

Heel RUS is a member of the Association of International Pharmaceutical Manufacturers (hereinafter AIPM) and fulfills all its obligations under the Association Code. In accordance with the requirement of Chapter 7 (Disclosure of Information on Transfer of Values in Favour of HealthCare Professionals and Organizations) of the AIPM Good Practice Code, Heel RUS publishes information on all the payments to Health Care Professionals and Organizations, thus providing transparency in disclosing data on the nature and extent of interaction with Health Care Professionals and Organizations, on its corporate website.

This methodological memorandum describes the company's approach to information disclosure and contents of the disclosed data. The company collects data on all cases of values transfer and strictly controls the accuracy of the data for publication.

Information disclosure in Russia is made via the company's website: [www.heel-russia.ru](http://www.heel-russia.ru)

### **2. Products Subject to Disclosure**

Heel RUS promotes a broad portfolio of products sold both by prescription and over-the-counter in the Russian market. Only details in cases of values transfer related to products sold by prescription are subject to disclosure.

### **3. Recipients**

**“Health Care Professionals”** are doctors and other health care specialists, heads of medical organizations, specialists in the field of pharmaceuticals (including pharmacy workers), heads of pharmacy organizations, as well as other specialists whose professional activities are related to pharmaceutical products and who, within their professional activities, have the right to prescribe, recommend, acquire, sell or apply pharmaceutical products.

**“Health Care Organizations”** are any legal entity that (i) is a health care, medical, pharmaceutical or scientific association or organization (regardless of its organizational form) – a hospital, a clinic, a foundation, a university or any other educational institution (with the exception of patient organizations) – having a registered office, a place of registration or a principal place of operation in Russia; or (ii) renders its services through one or more Health Care Professionals.

#### **4. Categories of Values Transfer**

- ***Sponsorship Contracts***

Heel RUS provides financial support to organizations involved in medical or scientific training of third parties, within the organization or conduction of educational or research events/activities.

Sponsorship packages can also include an opportunity of satellite symposium organization, sponsoring speakers and invitation of Health Care Professionals at scientific and educational events.

The transfer of values is to be carried out either directly to a Health Care Organization, or to an event organizer (or to another third party appointed by a Health Care Organization to hold the relevant event). In all the cases, information on values transfer is to be disclosed indicating a Health Care Organization that is a final beneficiary.

If expenses on food and beverages are an integral part of contributions to expenses related to an event organization, or sponsorship, carried out under sponsorship contracts with Health Care Organizations, information on food and beverage expenses shall be disclosed within disclosure of information on contributions to expenses related to an event organization.

- ***Payment for Services, Consultations and Related Expenses***

Heel RUS attracts a Health Care Professional/Organization for services rendering, if there is a business necessity in it and if the relevant Health Care Professional/Organization has all the necessary qualifications and meets the requirements necessary for the relevant services rendering. These services are to be paid at the rates corresponding to fair market prices.

Such services may include:

- speeches at meetings/events, including as the chairman;
- participation in consulting committees meetings;
- writing medical texts;
- training/educational materials preparing;
- general counseling/giving recommendations;

-services rendered in connection with third party's activities;  
-etc.

Payments made to Health Care Professionals are to be disclosed on an individual basis only after receiving a written consent of each Health Care Professional. If no written consent was obtained, the disclosure shall be made in general, without individual details.

As part of a written contract on paid services, payments for expenses related to the services rendering, which can include expenses on air and rail traveling, taxi, hotel accommodation and any visa related expenses, can be made. All the expenses are paid by Heel RUS to providers of transportation and/or accommodation services or events organizers.

Expenses incurred in favour of Health Care Professionals and those related to rendering services under the contract, including travel and accommodation expenses, are to be disclosed on an individual basis only after receiving a written consent of Health Care Professional. If no written consent was obtained, the disclosure shall be made in general, without individual details.

- ***Travel and Accommodation***

In order to improve professional knowledge of the medical community, Heel RUS provides support aimed at covering expenses of Health Care Professionals on travel and accommodation, incurred in order to participate in independent events and/or activities organized by Heel RUS.

Such expenses may include expenses on air and rail travel, hotel accommodation, taxis, and other travel expenses.

Expenses incurred in favour of Health Care Professionals and those related to rendering services under the contract, including travel and accommodation expenses, are to be disclosed on an individual basis only after receiving a written consent of Health Care Professional. If no written consent was obtained, the disclosure shall be made in general, without individual details.

If assistance provided to Health Care Organizations includes any support of Health Care Professionals in order to ensure their travel and accommodation within the framework of their participation in an event and the Health Care Professionals that benefit from such support are not specified, such a payment (transfer of values) falls into the Sponsorship Contracts category.

Payments for any organizational work are usually made directly to the providers of transport and/or accommodation services or the travel and/or accommodation organizer.

## **5. Data on Transfer of Values NOT SUBJECT to Disclosure**

- ***Informational and Educational Materials***

Information on transfer of informational and educational material shall not be disclosed due to the fact that such materials are inexpensive, are considered to be means of professional development for Health Care Professionals and are not included in categories of values that should be disclosed (according to the AIPM Code).

- ***Expenses for organizing events held by Heel RUS***

Expenses on organization of events held by Heel RUS (for example, premises renting, technical expenses, etc.) are not to be disclosed. In this case, the transfer of values to participants – for example, support for travel and accommodation or payment for services of performing Health Care Professionals are to be disclosed in the relevant expenses category.

## **6. Direct Transfer of Values**

An individual or a legal entity that is a holder of the account to which monetary funds are to be transferred is considered as a recipient (within the framework of the values transfer), information on whom shall be disclosed. All the data on cases of direct transfer of values shall be stored in the accounting system and included into financial statements of Heel RUS. After that, such data shall be included in the appropriate category of disclosed information.

## **7. Indirect Transfer of Values**

### ***Indirect Transfer of Values through Third Parties***

If third parties are appointed by a Health Care Organization to hold the relevant event (and if the ultimate beneficiary of such transfer of values is this Health Care Organization), information on such cases of values transfer is to be disclosed indicating this Health Care Organization. If an event is organized by several Health Care Organizations (without clear responsibilities distribution), the value is to be distributed equally between such Health Care Organizations.

If Heel RUS attracts third parties to provide transportation and/or accommodation services for Health Care Professionals that render services or receive support to ensure their presence at the events, information on such cases of values transfer is to be disclosed as part of the disclosure of information on the values transfer to Health Care Professionals in the relevant expenses category.

## **8. Period of Values Transfer**

If values transfer is a payment, the report shall disclose information on payments made in 2021 and those related to activities related to 2021. If a consent to disclose information in regard of healthcare specialist on such payments is obtained, such information is disclosed indicating each particular recipient of the values. If the consent is not obtained, information is to be disclosed on the general basis.

If values transfer is carried out under any long-term contracts, only cases of values transfer that occurred during the reporting year (2021) shall be disclosed.

If the values are transferred in kind, the transfer date in the report shall correspond to the date, when the recipient received the values.

## **9. Transfer of Values in Case of Event Cancellation**

If a Health Care Professional/Organization does not receive benefits due to his/her/its non-attendance at the event (or in case of the event cancellation), the relevant expenses are not to be disclosed – for example, expenses associated with a hotel accommodation booking canceling.

If in accordance with any service contracts Heel RUS pays any cancellation fees to Health Care Professionals/Organizations in connection with the event(s) cancellation, information on such payments shall be disclosed.

## **10. Consents Collection**

- ***Consent of Health Care Organization***

In Russia, information on Health Care Organizations is to be disclosed without the need for consent obtainment, since Health Care Organizations are legal entities.

- ***Consent of Health Care Professionals***

Heel RUS makes every effort to ensure a high level of disclosure of information on payments to Health Care Professionals, being individuals, while complying with data security requirements.

Data on a Health Care Professional on an individual basis can be disclosed only after obtaining a written consent from such Health Care Professional. If a Health Care Professional's consent has not been obtained, all the data shall be disclosed in general, without individual details.

## **11. Disclosure Procedure**

Publishing data on values transfer accompanied with a methodological note shall be carried out during the first six months after the end of the relevant reporting period (until June 30, inclusive).

Heel RUS keeps all the necessary records on disclosures for at least 3 years.

Information disclosure is carried out in Russian and in English.

## **12. Financial Data on Disclosure**

Disclosed Information is provided in Russian Roubles.

Information on values transfer disclosure contains no data on VAT. Only taxed withheld from the income source shall be taken into consideration.

