



GEDEON RICHTER

Methodological Note
for Transparency Reporting of Richter Gedeon Representative Office
in Belgrade (2017)

Last modified: 27th June 2018

FOREWORD

Promoting transparent relations or interactions between Richter and Patient Organizations, HCPs and HCOs to relevant stakeholders assists informed decision-making and helps to prevent unethical and illegal behaviour.

Under various applicable rules, regulations and other requirements, pharmaceutical companies must disclose engagements, payments and other Transfers of Value to Patient Organizations, HCPs and HCOs, either publicly or directly to specific stakeholders. Since Richter is a member company of Medicines for Europe (for further information please visit Medicines for Europe's website under <http://www.medicinesforeurope.com/medicines-for-europe/>), it must therefore directly apply the rules and requirements of the Code of Conduct of Medicines for Europe (please find under <http://www.medicinesforeurope.com/medicines-for-europe/#section-6>) to its activities or apply rules and requirements that are consistent with, and at least as comprehensive as the rules and requirements of the Medicines for Europe Code of Conduct.

Richter should disclose engagements and Transfers of Value that could potentially pose a conflict of interest or encourage the Recipients of the Transfers of Value to disclose them, where such disclosure would be in the best interest of patients or the public. Disclosure shall be made public by both the Company and the Affiliates on their own website, unless national rules impose the publication on another platform.

This Methodological Note applies to Richter.

Any terms defined in Annex I (Definitions) shall be applicable in this Methodological Note.

1 DISCLOSING TRANSFERS OF VALUE

Transparent relations and interactions between Richter and Patient Organizations, HCPs and HCOs assist informed decision-making and help to prevent unethical and illegal behaviour. The Company therefore shall disclose Transfers of Value that could potentially pose a conflict of interest, or to encourage the Recipients of the Transfers of Value to disclose them, where such disclosure would be in the best interest of patients or the public. Such disclosure shall include Transfers of Value made by a Third Party on behalf of Richter for the benefit of a Recipient and where Richter knows or is informed about the Recipient who will benefit from the Transfer of Value.

Richter shall disclose the amounts attributable to Transfers of Value which can be reasonably allocated to one of the categories set out below. Transfers of Value that are not listed below shall not be disclosed.

Transfers of Value will be disclosed on an individual, named basis:

Transfers of Value to HCPs:

- ***Fees for services and consultancy:*** aggregated honoraria (excluding expenses such as meals and drinks, travel and accommodation) paid by Richter to an HCP in exchange for the provision of services, such as serving as an expert on an advisory board, speaking at a company-organized educational event, participating in a focus group, etc. Fees paid in connection with R&D activities or market research, are excluded from the scope of this disclosure.

- **Meetings, educational support and site visits:** The Company and the Affiliates may choose one of the two options below for disclosure in this category.

Aggregate total amount of support provided to HCPs per individual conference or meeting as follows:

- **Sponsorship for attending a Third Party organized congress:**
 - name of congress;
 - aggregated amount spent for the congress; including the
 - number of HCPs financially supported to attend.
- **Site visits:** aggregated amount spent, including the number of HCPs financially supported to attend.
- **Company or Affiliate organized meetings:** aggregated amount spent, including the number of HCPs financially supported to attend.

Transfers of Value to HCOs:

- **Fees for services and consultancy:** aggregated honoraria (excluding expenses such as meals and drinks, travel and accommodation) paid by Richter to an HCO in exchange for the provision of services, such as serving as an expert on an advisory board, speaking at a company-organized educational event, participating in a focus group, etc. Fees paid in connection with R&D activities or market research are excluded from the scope of this disclosure.
- **Grants and donations:** aggregated monetary amounts and a brief description of the nature of the grant or donation (e.g. research grant, equipment donation, product donation, etc.).

2 PROCEDURAL RULES AS PER THE DISCLOSURE (DETAILED METHODOLOGICAL NOTE)

In line with the Medicines for Europe Code of Conduct which imposes an obligation on its member companies to adopt and disclose a Methodological Note, Richter shall set the following obligatory framework and procedural rules of disclosure:

OTC medicines are excluded. Disclosure requirements only apply to prescription-only medicines. Where Transfer of Value relates jointly prescription only and OTC medicinal products, only the portion pertaining to the prescription only medicinal products will be disclosed.

One disclosure per country. One transparency disclosure shall be issued for each country of operation in Europe showing all Transfers of Value made to Patient Organizations, HCPs and HCOs. Affiliates are responsible for capturing the Transfer of Value made in their country and for validating the accuracy of the data. Affiliates shall also observe all local laws and regulations.

Cross-country disclosure. A Transfer of Value to an HCP, an HCO or Patient Organization shall be reported in their primary place / country of practice. Should, for instance, a foreign HCP be

given Transfer of Value, the provider of the Transfer of Value will collect and send the details of such Transfer of Value to the Affiliate where the primary place of practice of the HCP locates, so that it can disclose the Transfer of Value locally.

Reporting period. In line with Section 5 of this Methodological Note, disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year. In case of short term activities within a defined timeframe, the start date of the activity shall be decisive, and the payment will be disclosed in the reporting period, in which the event takes place. In case of long term activities, the execution date of the relevant invoice shall determine the reporting period. (i.e.: certain service or consultancy agreements may be long term activities where Transfer of Value shall be reported in the period in which the individual invoices for specific activities are booked.) Grants and donations shall always be reported within the disclosure period when they are made.

Written agreements. When Richter provides financial support, significant indirect support and/or significant non-financial support to Patient Organizations, a written agreement shall always be in place which must state the amount of funding and also the purpose of the support. All engagements with HCPs and HCOs must be confirmed in writing or in contract with a clear description of the services or consultancy and the compensation (Transfer of Value).

Unique identifier. Unique identifier means the local identifier that facilitates the collection of Transfer of Value throughout Europe and across other Affiliates. Unique identifiers shall be provided in those countries where the local rules and regulations allow the use of it. In Hungary the unique identifier is the seal number of the physician, for other Recipients than physicians Richter does not apply any unique identifier (N/A).

Services and consultancy. Richter may engage Patient Organizations, HCPs and HCOs to provide necessary services, such as serving as experts on advisory boards, speaking engagement, participating in research, participating in focus group or market research, training and educating on products. In all cases, Richter must have a legitimate need for the service, pay no more than the fair market value and retain only the appropriate number of Patient Organizations, HCPs and HCOs necessary to effectively fulfil the service. HCPs must only be selected and engaged as service provides based on their qualifications, expertise and abilities to provide the service or consultancy.

Fees for services and consultancy. Service and consultancy fees shall be under corresponding service and consultancy agreements between the respective Patient Organization, HCP or HCO and Richter. Under this category Richter records any Transfer of Value (monetary and non-monetary) which is granted in exchange for services provided by a Patient Organization, HCP or a HCO to Richter at a fair market value. Payment shall only be made for work performed which shall be duly certified after the conclusion of the relevant agreement.

Meetings. Meetings between Richter and HCPs facilitate the beneficial and essential interactions, and they are held for educational, scientific or research reasons, and promotional purposes. Reasonable hospitality may be provided in connection with such meetings, but it shall always be secondary to the main purpose of the meeting. For Third Party organized congresses, where the number of attendants are not known by Richter, just the Transfer of Value will be shown without indicating the number (N/A) of Recipients.

Educational support. Richter may support scientific, medical, pharmaceutical and professional education by inviting and paying registration costs, travel, accommodation and reasonable hospitality to support individual HCPs to attend events that educate them in areas relevant to their field. Educational support may be provided for company-organized events or for

congresses and conferences organized by Third Parties.

Site visits. Visits to Richter's facilities shall have educational value and may never be provided as a means of improperly influencing a HCP. All site visits shall have a specific and full agenda.

Attendance or registration fees. The amount of attendance or registration fees eventwise and HCP-wise shall be collected by Richter during the reporting period and the amount will be disclosed depending on the disclosure option which the Company and the Affiliates have chosen.

Richter shall disclose Transfer of Values related to meetings, educational support and site visits as per individual conference or meeting.

Travel and accommodation costs. This includes, for example, hotel costs, flight, train, bus or taxi expenses as well as the costs of visa and travel insurance, if applicable. In case the travel is organized through an external travel agency, the related administrative costs will not be reported and disclosed.

Costs for internal events. Internal events are defined as events organized by Richter itself. Richter shall not charge attendance or registration fees for such events, therefore Transfer of Value shall not take place in this regard. In case travel and accommodation costs arise for Richter organized internal events, details of such costs shall be disclosed in the category provided for this purpose.

Grants and donations to HCOs. Grants and donations to HCOs shall serve the purpose of supporting healthcare goals, like research and education, and are documented and kept on record. They must never be provided as a means of improperly influencing a HCP or HCO, and must not influence decisions on research programs and on persons benefitting from donations (e.g. unrestricted grants). In case donation is made to a hospital as a whole or the department is not a legal entity in its own right, Richter shall disclose the donation under the name of the hospital. In case the donation is clearly intended for a specific department or unit within a hospital and this department is a legal entity in its own right, Richter shall disclose the details of the donation as well as the name of the department. Unrestricted contributions to HCOs that are not tied to a specific project or activity are prohibited.

Payments made to more than one Patient Organizations, HCPs or HCOs. Transfer of Value shall generally be disclosed on an individual basis. If an individual Transfer of Value can be allocated pro rata to the relevant Patient Organizations, HCPs or HCOs, these amounts shall be published under the name of the respective Patient Organizations, HCP or HCO. In case such allocation is not possible, each party is assumed to receive an equal share, and it shall be disclosed accordingly.

Indirect Transfer of Value to Patient Organizations, HCPs and HCOs. In case Richter becomes aware that Transfer of Value granted to a Third Party have been passed on to a Patient Organization, HCP or a HCO, or those have benefitted from such Transfer of Value, Richter shall disclose the details of each of those Transfer of Value under the name of the relevant Patient Organization, HCP or HCO in line with the applicable data privacy regulations detailed in Section 6 of this Methodological Note.

Multi-year contracts. In case the Transfer of Value relates to a multi-year contract, only those Transfers of Value shall be reported which refer to the period when the individual invoices for specific activities are settled and the payment is transferred to the Recipient's bank account.

Exclusion of R&D and market research. Fees paid in connection with R&D activities and

market research are excluded from the scope of the disclosure.

Inclusion of VAT and other taxes. The disclosed data are gross amounts, VAT included.

Disclosure shall be always made in the official local currency of the Recipient's country of primary practice. Transfer of Value shall be recorded in that currency in which the transaction takes place. The final disclosure is shown in Serbian Dinars (RSD) For transactions where conversion is necessary, the calculation shall be applied at the Hungarian National Bank's official exchange rate valid on the date (11th June 2018).

Language. The Company and the Affiliates shall make disclosures available both in their own languages and in English.

3 PLATFORM FOR DISCLOSURE

The Company and the Affiliates shall disclose transparency information on their local websites or on a separate disclosure platform if required by the local rules and regulations. Richter's transparency disclosure shall be accessible via www.richter.rs in Serbia.

All disclosed transparency information shall remain accessible online for a reasonable period of time, preferably for a period of three (3) years.

4 FIRST DATE OF DISCLOSURE AND THE FREQUENCY OF DISCLOSING

All relevant Transfers of Value allocated in 2017 will have to be disclosed during the following reporting period, starting from January 2018 and at the latest by 30th June, 2018.

Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year. The first reporting period shall be the calendar year 2017 and the first disclosures shall be made from January 2018.

5 DATA PRIVACY AND CONSENT

Richter must always comply with all applicable legal regulations and rules on privacy, data protection, processing of personal data, data security and related sectorial policies, when Richter processes personal data received from, collected about, referring to or connected to HCPs, HCOs, patients and Patient Organizations. In case the fulfilment of Richter's transparency obligations results in the processing of personal data, inter alia the publication and disclosure of such data, the processing of personal data shall all time comply with the data protection rules as detailed in Richter's Global Privacy Policy.

The data controller is Gedeon Richter Plc.

Every human being is entitled to the protection of his/her privacy and personal data according to legal regulations. This fundamental right also extends to personal data processing (including their collection, use, publication and disclosure) of all individuals. So that Richter can process personal data, a legal basis is always needed. The most usual legal basis is when the data subject gives his/her consent to a specific data processing. The requirements of a lawful consent are strict; Richter must give a prior, clear, detailed and transparent information about the circumstances of the data processing towards the data subject, and the data subject shall be able to give his/her declaration about giving his/her consent without any influence.

In order to fulfil its transparency obligations and be able to disclose the Transfers of Value provided to Healthcare Professionals on a name basis or in another identifiable form, Richter is required to have a proper legal basis. Based on the above, in connection with this data processing (publication/disclosure), Richter's legal basis for personal data processing shall be the voluntarily given consent of the Healthcare Professional based on previous detailed information. For this reason, if a HCP does not give his/her consent to the disclosure of his/her personal data pertaining to a certain Transfer of Value, such personal data shall not be disclosed in a way where data could be linked to the given HCP or the HCP could be identified in any way. In such case Richter must disclose the Transfer of Value connected to a certain HCP without name. If the consent required for the disclosure is not given by several HCPs, the Transfer of Value data should be disclosed only in an aggregated form, indicating the number of the HCPs affected by such aggregation.

As regards the technical side, Richter handles the information being provided to HCPs about data processing and the declaration about giving consent by placing a specific section on transparency and data protection in the main contract to be concluded with an HCP, and encloses a detailed privacy information notice as well as a separate declaration to the contract. An HCP may give his/her declaration about giving or not giving his/her consent to the disclosure of his/her personal data related to the Transfer of Value by filling the declaration form.

Data protection related remarks and questions may be addressed to Gedeon Richter Plc. under dataprotection@richter.rs email address or to +381 11 660 8998 phone number. The supervisory authority for handling data protection issues in Serbia is the Commissioner for information of public importance and personal data protection (postal address: Bulevar Kralja Aleksandra 15, Belgrade, Serbia; phone: +381 11 3408-900; fax: +381 11 3343 379; email: office@poverenik.rs; web: www.poverenik.rs).

ANNEX I TO THE METHODOLOGICAL NOTE

DEFINITIONS

"Affiliate" means any legal entity that is directly or indirectly controlled by or is under common control with Gedeon Richter Plc. Control means that an entity or person alone or jointly with others has the legal or actual ability to control the voting, or control and direct the management, of another entity, whether by contract or otherwise.

"Fair Market Value" means the value that would be paid as a result of bona fide bargaining between well-informed parties in arm's-length transactions for the goods or services to be provided. The value shall consider the nature or quality of the goods or services to be provided, the qualifications and experience of the provider, the geographic location where goods or services are to be provided, the nature of the market for the goods or services to be provided, and the prevailing rates for similar goods or services;

"HCP" means a healthcare professional who is a member of the medical, dental, pharmacy, and nursing profession and any other person who, in the course of his/her professional activity, is qualified or permitted to prescribe, supply, administer, purchase, recommend, reimburse, pay for or acquire a medicine, or influence or authorize any of the foregoing. Examples of HCPs are physicians, nurses, medical assistants, pharmacists, paramedics, product formulary committee members, clinical investigators, and public and private hospital employees;

"HCO" means a healthcare organization, an entity (i) that is a healthcare, medical or scientific organization or company (irrespective of its legal or organizational form), such as hospitals, clinics, universities or other educational institutions or associations or (ii) through which one or several HCPs supply services;

"Company" means Gedeon Richter Plc. (1103 Budapest, Gyömrői út 19-21., Hungary);

"medicinal product" means any substance or combination of substances presented for treating or preventing disease in human beings. Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product. In this Pharma Law Manual this definition is used for Richter's any and all products that qualify as medicinal product;

"over the counter medicinal product" or **"OTC medicinal product"** means medicinal products which can be purchased without a medical prescription;

"Patient Organization" means non-profit organizations which are patient-focused, and in which patients or their carers represent a majority of members in their governing bodies;

"prescription only medicinal product" means medicinal products which can be purchased only with a medicinal prescription;

"Recipient" means any HCP, HCO or Patient Organization as applicable, to whom Richter provides Transfer of Value;

"Richter" means Gedeon Richter Plc. and its Affiliates;

"Third Party" means any entity or person who represents Richter or acts on its behalf, such as

distributors and other third parties providing any marketing, promotion and third party sales force services. The term "Third Party" also includes consultants, agents, sub-contractors, joint venture partners, brokers, service providers, suppliers and any other persons when acting on behalf of Richter;

"Transfer of Value" means 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 Richter for the benefit of a Recipient. Indirect transfers of value are those made on behalf of Richter for the benefit of a Recipient, or transfers of value made through an intermediate and where Richter knows or can identify the HCP/HCO that will benefit from the Transfer of Value.