

Methodological note

for transparency reporting

of Richter Gedeon Representative office in Belgrade (2022)

Last modified: 23rd June 2023

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's 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:

A. TRANSFERS OF VALUE TO PATIENT ORGANIZATIONS

Support: financial and in-kind support: All provided financial support and/or significant non-monetary support, whether direct or indirect, are publicly available by listing the Patient Organizations to which the support was provided. Said disclosure includes:

- Name of Patient Organization
- Registered seat of the Patient Organization or place of operation if the purpose of

ToV is to support that operation specifically

- Category of ToV: Fee for service/In kind support/Financial support
- The date when the recipient received the ToV
- Location of the Event
- **Purpos/Description of the ToV:** e.g. unrestricted grant, sponsorship of a specific meeting, or to support a publication, supporting healthcare or research
- Expense Details (if not directly related to the performance of a fee for service contract): Type (e.g. travel, accommodation, meals and drinks) of expense and amount per type
- Aggregated Amount/Value of ToV

Such disclosure is done by Company separately at the Affiliate level. This information is updated at least once a year.

Fee for services: contracted services per Patient Organization, including a description of the nature of the Transfers of Value (educational summer camp, disease awareness world day, development of information brochures for an awareness campaign, etc.) and the amount provided. At least once a year the amounts paid in the previous year for services rendered by Patient Organizations are published in a breakdown according to Patient Organization. The nature of such services is disclosed in a way that is sufficiently complete to enable the average reader to form an understanding of the nature of the arrangement. Confidential information in such agreements remain confidential. Such disclosure is done by the Company separately at the Affiliate level.

B. TRANSFERS OF VALUE TO HCPS

Fees for services and consultancy: aggregated (for the reporting period) honoraria (excluding expenses directly related to performance of the contracted service 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. If an HCP provides contracted services through a consultancy or personal services company controlled by them or their family, then for disclosure purposes the engagement is to be treated as if the Transfer of Value was made to the individual. Fees paid in connection with R&D activities or anonymous market research, are excluded from the scope of this disclosure. The research & development exception applies only to fees paid. The market research exception in respect of fees applies only to genuinely anonymous market research where it is not possible for Richter to know or deduce the identity of the respondents. Said disclosure includes:

- Name of HCP
- HCP's principal place of business
- Unique Identifier (if relevant)
- The date when the recipient received the ToV
- Purpose/Description of the ToV: a legitimate business need, e.g. education and training, advisory boards and consultant meetings, market research, speaker training, or continuing health education
- Expense Details (if not directly related to the performance of a fee for service contract): Type (e.g. travel, accommodation, meals and drinks) of expense and amount pertype
- Aggregated Amount/Value of ToV

Support to attend meetings, educational support and site visits

To be reported:

- registration fees to attend a Third Party congress/conference, including virtual meetings, and
- travel and accommodation to attend a meeting including Third Party meetings, Richter organized meetings and site visits.

If there is no direct cost (other than food and drinks) connected to a meeting there—is no Transfer of Value to disclose. For Richter organized meetings, items such as room rental and audiovisual support do not confer any benefit to individual delegates and are not Transfers of Value. Meals included as part of a conference registration 'package' are relatively insignificant and should not be deducted. Where Richter receives a number of free conference registrations as part of a sponsorship package and gives these to HCPs, the deemed value of the transfer will be the price that individual recipients would have paid for themselves at the time the arrangements were made.

The Company and the Affiliates may choose one of the two options below for disclosure in this category:

OPTION 1

Total number (but not actual monetary value) of events, for which an individual HCP has received support (which may include payment of registration fees, travel and/or hotel costs). Support is disclosed per individual HCP as detailed below:

- Name of HCP
- HCP's principal place of business
- **Unique Identifier** (if relevant)
- Number of Third Party Organized Conferences (Domestic, European, International)
- Number of Company Organized Meetings (Domestic, European, International)
- Number of Company Organized Site Visits (Domestic, European, International)
- **Aggregated number of recipients included in the aggregate disclosure** (for HCPs who did not consent to publish their data)

OPTION 2

Aggregate (for the reporting period) total amount of support provided to HCPs per individual (Third Party or company organized) conference, meeting or site visit as follows:

- Category: Third Party organized congress or Company organized Meeting/Site Visits
- Name of congress;
- Number of HCP recipient
- Aggregate support to HCPs for meetings, Educational support and Site visits

Richter discloses Transfer of Values related to meetings, educational support and site visits as per individual conference or meeting (Option 2).

C. TRANSFERS OF VALUE TO HCOs

The following needs to be disclosed:

- Name of HCO
- **Location of the Organization** (Registered seat of the HCO or place of operation if the purpose of ToV is to support that operation specifically)
- Category of ToV: Fee for services or consultancy/Grants and donations
- The date when the recipient received the ToV

- Location of the Event
- Purpose/Description of the ToV: a legitimate business need, e.g. education and training, advisory boards and consultant meetings, market research, speaker training, or continuing health education, support the improvement of healthcare, medical science and education
- Expense Details (if not directly related to the performance of a fee for service contract): Type (e.g. travel, accommodation, meals and drinks) of expense and amount per type
- Aggregated Amount/Value of ToV

Fees for services and consultancy: aggregated (for the reporting period) honoraria (excluding expenses directly related to performance of the contracted service 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. If Richter contracts a HCO for the services of a specific HCP whom they employ, then for disclosure purposes the engagement is to be treated as if the Transfer of Value was made to the individual, even if the individual performing the service was not directly compensated. If there is no requirement for specific individuals to perform the work, then for disclosure purposes the engagement is to be treated as if the Transfer of Value was made to the HCO. Fees paid in connection with R&D activities or anonymous market research are excluded from the scope of this disclosure. The research & development exception applies only to fees paid. The market research exception in respect of fees applies only to genuinely anonymous market research where it is not possible for Richter to know or deduce the identity of the respondents.

Grants and donations:

To be reported:

- both financial and in-kind aggregated (for the reporting period) monetary amounts and a brief description of the nature of the grant or donation (e.g. research grant, equipment donation, product donation etc.) and where not obvious, its purpose (e.g. "to increase lung cancer screening capacity" or "to support pandemic relief") for each HCO.
- Equipment provided to a HCO for the purposes of a study does not need to be disclosed as long as the equipment is taken back at the end of the activity. If the equipment is left in the possession of the HCO, it must be disclosed as a donation at the current Fair Market Value of the equipment. In-kind contributions to HCOs must always be disclosed at Fair Market Value, even if the donating company has written off all or part of the value in its own books.

Sponsorship of the HCOs' activities and events

To be reported:

• The total amount of sponsorship for the reporting period.

If there is no direct cost (other than food and drinks) connected to a meeting there is no Transfer of Value to disclose. For Richter organized meetings, items such as room rental and audiovisual support do not confer any benefit to individual delegates and are not Transfers of Value.

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

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

OTC medicines are excluded. Disclosure requirements only apply to prescription-only medicines, unless national requirements or local ethical codes require them to be included. Where Richter's product portfolio includes both prescription only and OTC medicinal products then meetings, activities and Transfers of Value that solely or partly involve prescription-only medicinal products are to be regarded as being fully within the scope of disclosure under this Methodological Note.

One disclosure per country. One announcement from the Representative Office will be published separately for Serbia, with a presentation of all value transfers made to patient organizations, HCPs and HCOs. The representative office is responsible for recording the transfer of value carried out in Serbia, as well as for checking the accuracy of the data.

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 are 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 is 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 determines the reporting period (i.e. certain service or consultancy agreements may be long term activities where Transfer of Value is reported in the period in which the individual invoices for specific activities are booked). Grants and donations are always 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 is always in place which states the amount of funding and also the purpose of the support. All engagements with HCPs and HCOs are 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.

Services and consultancy. The representative office may engage patient organizations, healthcare professionals and healthcare organizations to provide necessary services, such as participation in advisory boards as experts, as speakers at educational events organized by the Company, participation in focus groups and market research, training and product education. In each case the Company must have a legitimate need for these services, pay no more than fair market value taking into account the skills, experience, job role, prominence and location of the individual performing the work and maintain an appropriate number of patient organizations, health care professionals and health care organizations necessary to provide these services in an efficient manner. Health professionals must only be selected and engaged as service providers based on their qualifications, expertise and ability to provide a service or consultation. The engagement must not be offered or established with the intent to induce the health care organization or health care professional to supply, advertise, prescribe, approve, reimburse, purchase or recommend a particular product, influence the outcome of clinical trials, or otherwise inappropriately brings benefits to business activities. Engagement for services and consultations must be in accordance with the Law on Medicines and Medical Devices of the Republic of Serbia, by-laws adopted on the basis of that Law, as well as internal acts in force in the Company and the Representative Office.

Fees for services and consultancy. Service and consultancy fees are 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 nonmonetary) which is granted in exchange for services provided by a Patient Organization, HCP or a HCO to Richter at a Fair Market Value considering the skills, experience, job role, prominence and location of the individual performing the work. Payments are only made for work performed which are 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 is always secondary to the main purpose of the meeting. For Third Party organized congresses, where the number of attendants is 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. The decision on who should receive support for educational purposes should be based on objectively defined criteria that are directly related to the educational needs of the recipient and the educational value of the program.

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

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

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 are not reported and disclosed.

Richter discloses Transfer of Values related to meetings, educational support and site visits as per individual conference or meeting (Option 2).

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

Grants and donations to HCOs. Grants and donations to HCOs serve the purpose of supporting healthcare goals, like research and education, and are documented and kept on record. They are never provided as a means of improperly influencing an HCP or HCO, and does 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 discloses 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 discloses 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 is generally 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 are 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 is 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 discloses 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 and timing. In case the Transfer of Value relates to a multi-year contract, or where an event happened during the reporting period and the liability to pay was incurred but the member of the healthcare community has invoiced Richter in another reporting period, only those Transfers of Value are 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 anonymous market research. Fees paid in connection with R&D activities and market research are excluded from the scope of the disclosure. The research & development exception applies only to fees paid. The market research exception in respect of fees applies only to genuinely anonymous market research where it is not possible for Richter to know or deduce the identity of the respondents.

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

Disclosure is always made in the official local currency of the Recipient's country of primary practice. The transfer of value will be recorded in the currency in which the transaction itself took place. For transactions requiring conversion, the calculation should be applied at the official exchange rate in effect on the day the transaction is posted to the Company's applicable financial system.

Language. The representative office will publish data in Serbian and English.

3 PLATFORM, LOCATION AND FORMAT OF DISCLOSURE

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

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

4 DATE OF PUBLICATION AND DYNAMICS OF PUBLICATION

All relevant Transfers of Value belonging to 2022 will have to be disclosed during the next reporting period, starting from January 2023 and no later than 30 June 2023.

Disclosures are made on an annual basis and each reporting period shall cover a full calendar year.

5 DATA PRIVACY AND CONSENT

Richter always complies 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 complies all time 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 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 is 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 will 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 Transfers of Value data are disclosed only in an aggregated form, indicating the number of the HCPs affected by such aggregation.

If an HCP withdraws consent for the disclosure of their data, the reporting company must update the published disclosure report with that person's data aggregated as soon as possible, but at the latest within 30 days after receiving the withdrawal request.

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 Representative office: dpo@richter.rs or by calling the number +381 11 660 8998. The supervisory authority for dealing with issues related to data protection in Serbia is the Commissioner for Information of Public Importance and Protection of Personal Data (postal address: Bulevar Kralja Aleksandra 15, Belgrade, Serbia; phone number: +381 11 3408-900; fax : +381 11 3343 379; email: office@poverenik.rs; web: www.poverenik.rs).

Additionally, Data protection related remarks and questions may be addressed to Gedeon Richter Plc. under dataprotection@richter.hu email address. The supervisory authority for handling data

protection issues in Hungary is the National Authority for Data Protection and Freedom of Information (NAIH; postal address: H-1363 Budapest, Pf.: 9., Hungary; seat: H-1055 Budapest, Falk Miksa utca 9-11., Hungary; phone: +36 (1) 391-1400; fax:

+36 (1) 391-1410; email: ugyfelszolgalat@naih.hu; web: www.naih.hu).

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 independent 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 in the provider's country. Where a person or their employer/organization is to be paid for their time in providing a service, Fair Market Value must consider the prevailing rate in the individual's country of primary practice, even if the service is provided elsewhere; The principle of Fair Market Value generally applies to collaborations with members of the Healthcare Community.

"Healthcare Community" means HCPs, HCOs, patients and Patient Organizations. Also includes any other person or organization that is involved in the regulation, approval, control or supply of medicines, or that communicates about medicines in a professional capacity (for example a medical journalist, but excluding Richter Employees or representatives) to HCPs, HCOs or Patient Organizations.

"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, dispense, supply, administer, purchase, recommend, reimburse, pay for, administer 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. This term also includes any official or employee of a government agency or other organization (whether in the public or private sector) who may purchase, supply, recommend or administer medicinal products. It also includes any employee of a pharmaceutical company whose primary occupation is that of a practising healthcare professional, but it does not include (i.) any other employee and (ii.) pharmaceutical wholesalers, distributors and their 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, foundations, universities or other teaching institutions, learned societies or associations or (ii) through which one or several HCPs supply healthcare services. Wholesalers, distributors, and similar commercial intermediaries are not considered HCOs. Pharmacy businesses are always healthcare organizations, even if they are retailers and regardless of their ownership or ownership structure.

"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