



A.MENARINI
PHARMACEUTICALS IRELAND LTD
Healthcare for Life

Transfer of Value Disclosure

Methodological Note

1. Introduction

This methodological note is intended to help readers understand how the Transfers of Value (ToVs) from A. Menarini Pharmaceuticals Ireland Ltd (A. Menarini) to Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs) within Ireland have been collated and reported.

All Transfers of Value relate to prescription-only medicines, i.e. those medicines that must be prescribed by a suitably qualified HCP.

Excluded from disclosure are items of medical utility (governed by Article 9 of the EFPIA HCP Code), meals and drinks (governed by Article 10 of the EFPIA HCP Code), medical samples (governed by Article 16 of the HCP Code) or transfers which are part of ordinary course purchases and sales of medicinal products.

Full details of the EFPIA Disclosure code can be found at <http://transparency.efpia.eu/>

2. Definition of Direct and Indirect Transfers of Value

The following definitions apply throughout this report:

- Direct ToVs are defined as those ToVs, payments or in kind, made directly by A.Menarini to the benefitting HCPs/HCOs.
- Indirect ToVs are defined as those ToVs made through an intermediary (third party) on behalf of A.Menarini for the benefit of a HCP/HCO where A.Menarini knows or can identify the HCP/HCO that benefits from the ToVs.

3. Cross-Border Transfers

In the case of any ToV's made by A.Menarini Ireland to a HCP or HCO who's "home country" (country of principal practice) is not Ireland, this ToV will be disclosed in the recipient's home country. For example, A.Menarini Ireland might make ToVs to a German HCP. Any ToVs made by, or on behalf of, A.Menarini Ireland to recipients within EFPIA countries will be notified to the Menarini Group affiliate in that recipient's home country and disclosed by them. If no Menarini Group affiliate is in place in that country, it will appear on the Menarini.com website.

4. Transfer of Value categories and methodologies

The EFPIA disclosure template prescribes the following categories of transfer of value:

- Donations and grants to a HCO
- Contribution to costs related to events to a HCO/HCP, such as:
 - Sponsorship agreements
 - Registration fees
 - Travel and accommodation
- Fees for service and consultancy to a HCO/HCP
 - Fees for service and consultancy
 - Expenses related to fees for service and consultancy
- Research and development

The methodologies used under each category are given below:



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4.1 Transfers of Value related to Donations and Grants

Grants to a hospital/university department or teaching institution are disclosed in the name of the legal entity that is the Recipient of the ToV – this may be the hospital, university or independent department within these organisations.

4.2 Transfer of Values Related to Contribution to Costs of Events

Events are defined as promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events.

Sponsorship agreements – A.Menarini may sponsor HCOs for arranging educational events. These may be direct contributions to faculties in support of their event or indirect payments to venues to cover the costs of such events. All will be disclosed as a ToV to the HCO who is the ultimate beneficiary.

Registration fees - whenever registration fees are paid for an event organised or sponsored by or on behalf of A.Menarini, they are disclosed in the name of the benefitting HCP or HCO. The total amount of registration fees paid in a given year to a HCO will be disclosed on an individual basis in the name of the HCO. The total amount of Registration Fees paid in a given year to a HCP who is the clearly identifiable recipient is disclosed under “Contribution to Costs of Events”.

Travel & accommodation – ToVs covered under the “Travel and Accommodation” category include costs of transportation and accommodation. In general, ToVs related to travel and accommodation are disclosed at first level recipient basis. If the ToVs are made through an HCO but related to a clearly identifiable HCP, they will be made against the HCP name. For ToVs related to travel and accommodation for a group of HCPs such as group transportation by bus, the total cost is divided equally among the number of benefitting HCPs. In the case of cancellation charges and “no-shows”, no disclosure will be made.

4.3 Transfer of Values Related to Contribution to Fees for Service and Consultancy

ToVs covered under the “Fees for Service and Consultancy” category, whether made directly or through a third party to an HCP/HCO, include speakers’ fees, medical writing, data analysis, development of education material, interviews etc. Some examples are given below:

- a. Advisory Boards - HCPs give A.Menarini advice on particular aspects of its strategy or the use of its medicines. A.Menarini may pay an honorarium to each participant.
- b. Speaker meetings - HCPs are engaged to educate other HCPs on therapeutic areas associated with A.Menarini’s medicines. A.Menarini may pay an honorarium to each speaker.
- c. Market research - small ToVs might be made to HCPs in return for answering questions about A.Menarini products and / or a therapeutic area. A.Menarini only participates in “blind” market research where it does not know the identities of the participants. A.Menarini has therefore not reported any ToVs for market research activities.

All such payments are formalised through a consultancy agreement.



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Related expenses - In conjunction with consultancy agreements, A.Menarini may reimburse a HCP/HCO for travel expenses incurred or pay these items directly. Where separately identifiable, these will be included in "Fees for Service and Consultancy – related expenses"

4.4 Transfer of Values Related to Research and Development

ToVs related to the following Research and Development activities are disclosed under the "Research and Development" category in aggregate form whenever they fall under the definition of Research and Development by the EFPIA Disclosure Code.

5. Disclosure

With effect from 1 January 2022, A.Menarini Ireland used legitimate interests (rather than written consent) as the legal basis for processing and disclosing ToV data under the applicable data protection legislation (the EU General Data Protection Regulation, as supplemented in Ireland by the Irish Data Protection Act 1988 and 2003).

The publishing of ToV data on an individual named basis serves important legitimate interests, including:

- Demonstrating transparency in relation to the pharmaceutical industry's relationships with HCPs
- Promoting a culture of integrity of transactions between pharmaceutical companies and HCPs
- Decreasing any perception of influence on HCPs by the pharmaceutical industry
- Instilling public and patient confidence in the integrity and independence of HCPs

Data related to applications for support will be stored on our database (or those of other affiliates) and shared with the IPHA to be used for publicly reporting payments or other transfers of value made by us to you as required by our industry Code of Practice. Further information on the disclosure of ToV can be found on the website www.transferofvalue.ie

More specifically, we may collect, process and disclose data including name, principal practice address and total value of any direct or indirect transfers of value for the benefit of a HCP in the relevant reporting period. Such disclosure will be in accordance with our Privacy Notice which can be found at www.menarini.ie and our legitimate interest. Rights under our privacy policy can be exercised by contacting ireland@menarini.ie

In disclosing such personal data to the IPHA to be made publicly available on the website www.transferofvalue.ie, the IPHA will be an independent data controller in respect of such data. The IPHA's privacy notice is available at www.ipha.ie.



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6. Financial Aspects

The following must be noted with regards to methodology and business decisions associated with the collection and disclosure of the ToVs:

- Data gathering – Transfer data is collated using the company's in house finance and reporting systems
- Timing: A.Menarini ToV disclosures correspond to the period to which the event occurred for which the ToV payment is being made. Therefore, following the standard accrual accounting concept, i.e. a payment made in 2024 relating to an event in 2023 will not be included in the 2024 report. Similarly a payment in 2024 being a deposit for a 2025 event will be disclosed in the 2025 ToV report.
- Currency: All ToV's are disclosed in Euro. Any payments incurred in other currencies are converted at the prevailing spot rates, corresponding to the cost to the company.
- VAT: Where applicable, VAT is included.
- Multi-year contracts: Transfers correspond to the payment amount and date, i.e. a 3-year contract with equal annual payments will be disclosed in 3 separate years.

7. Publication of report

Publication of data will be made on a central report hosted by IPHA at www.transferofvalue.ie within 6 months of the end of each calendar year. The data will remain published for 3 years from the time of disclosure, after which they will be deleted by the IPHA. A.Menarini are obliged to hold records for at least 5 years.

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