

SOP	Methodological note	Berlin-Chemie/A.Menarini Ceska republika s.r.o.
Strana 1 z 5	AIFP ToV Disclosure	BC-CZ-SOP-TOV-01

Methodological note

AIFP ToV Disclosure

	Jméno	Oddělení/pozice	Datum	
Účinnost:			1. 7. 2026	
				Podpis
Lokalizováno:	XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXX	30. 6. 2026	
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1. Definitions

1. **Recipients:** Any Healthcare Professional (HCP) or Organisation (HCO) that carries out a profession or principle activity or that has the main domicile or legal head office in Europe:
 - a. **HCP:** Any natural person that is a member of the medical, dental, pharmacy, or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a Medicinal Product and whose primary practice, principal professional address or place of incorporation is in Europe. The definition of HCPs includes: (i) any official or state employee, agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply, recommend or administer Medicinal Products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of Medicinal Products.
 - b. **HCO:** Any legal person/entity (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for Patient Organisations) whose business address, place of incorporation or primary place of operation is in the Czech Republic or (ii) through which one or more HCPs provide services.
 - c. **Patient Organisation:** Non-for-profit legal person/entity (including the umbrella organisation to which it belongs and including patient organizations as defined by Czech law), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is in the Czech Republic.

Treatment of retired and deceased HCPs: the Company publishes both the TOVs made to retired HCPs and dead ones in relation to the gathered Privacy consent.

2. **Transfer of Value (TOV):** Economic transfers whether direct or indirect, both in cash or kind, carried out for either promotional aims or for the development and commercialisation of pharmaceuticals for human use subject to medical prescription:
 - Research and development of new drugs through trials conducted in hospitals, universities and in public or private Healthcare Organizations;
 - Scientific consulting;
 - All the events of a promotional nature whether scientific or professional such as congresses, conferences, symposiums and other similar initiatives organised or sponsored by pharmaceutical companies:
 - Scientific seminar and conferences which provide information and updates;
 - Conferences and Continuing Medical Education courses organized by public structures, universities and scientific communities and accredited CME providers.
 - Advisory Boards
 - visits to company plants
 - Investigator Meetings finalised towards clinical studies and not interventional
 - Donations and grants (including free-of-charge leases) include all the supplies, in cash or kind, destined either directly or indirectly to the HCOs.

2. Disclosure's scope

1. **Products concerned:** the EFPIA Report includes TOV made for Prescribed Only Medicines.
2. **Company concerned:** in addition to the TOV made by Berlin-Chemie/A.Menarini Ceska republika s.r.o., the data includes TOVs made by Fondazione Internazionale Menarini, Research and Development from Menarini Ricerche spa, and other Menarini Group's subsidiaries to Czech HCPs and HCOs (and POs if necessary)

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3. **Excluded ToVs:**
 - a. TOV for Over the Counter Medicines (and medical devices if applicable)
 - b. meals and beverages
 - c. informational and educational materials, MUIs, samples
4. Regular buying and selling activities that take place between the company and HCPs and HCOs **ToVs date**
5. **Direct ToVs:** the direct transfers are those carried out directly between the company for the benefit of the recipient.
6. **Indirect ToVs:** the indirect transfers are those carried out on behalf of the company by a third party. If a transfer of value has been made to an individual Healthcare Professional indirectly via a Healthcare structure or third party, this data shall be disclosed on an individual basis where possible, and only once.
7. **Non-monetary ToVs:** not applicable
8. **ToVs in case of partial attendances or cancellation and refund:** any cost paid for invited but not attended HCP aren't disclosed neither in the individual section nor in the aggregated one.
9. **Cross-border activities:** TOVs from the Group's subsidiaries to Czech HCPs and HCOs are included, vice versa TOVs from the Czech subsidiary to foreign HCPs and HCOs are excluded and communicated to the Menarini Company located in the resident country of the recipient.
10. **R&D:** The transfers of value connected to the Research and Development include those activities planned or carried out with the aim of developing non-clinical studies as defined in the Good Laboratory Practices, clinical studies, as governed by Directive 2001/20/CE, and non-intervention studies that are prospective in their nature and that involve the gathering of information on patients by doctors for the study itself.
11. **Voluntary disclosure** (anything disclosed beyond the national Code): not applied

3. Specific considerations

1. **Country unique identifier** (if needed, specify which identifier is used and for which purpose): not applied
2. **Self-incorporated HCP** (depending on the local legislation, qualified as individual or company): not applicable
3. **Multi-year agreements:** the ToVs relating to an event involving two or more ToVs to the same HCP and/or HCO (at different points in time and spanning multiple years) has been published only once for each event in the year following the year in which the last transfer of value occurs.
4. **Country specificities:** no specificities
5. **Quality Checks** (optional for pre-disclosure)

4. Data protection legal basis

1. **Consent collection** (inc. consent withdrawal): the Company collects the Privacy consent from the **Healthcare Professionals** for disclosure of each TOV. If the HCP does not give his/her consent to EFPIA publication, the Company disclose the data on an aggregate basis. The HCPs have the legal right to withdraw at any time the consent previously granted to the Company for the publication of TOVs on an individual basis: if the HCP exercises this right, the Company must comply with the request within 30 days of receipt of the revocation by publishing the new report without the HCP data in the individual section and putting them in the aggregate one
2. **Consent collection** for the disclosure of ToVs data in relation to HCO or PO: as a legal entities, HCOs and POs are informed about Company transparency reporting obligations in writing, but privacy consent collection is not required. ToVs in connection to interactions with HCOs and POs are disclosed at the individual level. Research and Development ToVs in each Reporting Period must be disclosed by Company on an aggregate basis.
3. **Partial consent:** not applicable

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4. **Legitimate interest** (inc. balancing test, right to object): HCP has the right to object, at any time, to the processing of his/her data based on Article 6 para. 1 sent. 1 f) GDPR (data processing on the basis of a weighing of interests) or Article 6 para. 1 sent. 1 e) GDPR (data processing in the public interest) if there are reasons for doing so that result from his/her particular situation. If HCP file an objection, Company will no longer process Personal Data unless Company can prove compelling reasons for the processing worthy of protection that outweighs his/her interests, rights, and freedoms, or the processing serves the assertion, exercise, or defense of legal claims. To access his/her data, HCP can contact Berlin-Chemie Data Protection Officer at: dpo.cz@berlin-chemie.com.

5. Form of Disclosure

1. **Date of publication:** June 30th for the ToV data of previous calendar year
2. **Disclosure platform:** AIFP website
3. **Disclosure language:** Czech

6. Disclosure financial data

1. **Currency:** CZK
2. **VAT:** all TOVs are net of VAT
3. **WHT:** all TOVs are gross of withholding tax
4. **Calculation rules** (e.g., in-kind ToVs): not applicable
5. **Criteria:** accruals-based