

Shionogi Europe - Methodological Notes

The definition of a Transfer of Value (ToV) for the UK includes direct and indirect ToV, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of a prescription only medicine (POM) exclusively for human use.

Direct ToVs: made directly by Shionogi for the benefit of a Recipient.

Indirect ToVs: made on behalf of Shionogi for the benefit of a Recipient, or those made through a Third Party (e.g., a meetings and events agency) and where Shionogi knows or can identify the Recipient that will benefit from the Transfer of Value.

What payments do we disclose?

- Fees for service and related expenses, Donations, Grants, Sponsorships to HCOs, financial support to Patient Organisations (POs) and Research and Development- (R&D) related payments.
- ToVs related to travel (e.g., flight ticket), accommodation (e.g., hotel room cost) and registration fees, will be included in the calendar year in which we executed the actual payment or reimbursement in our financial systems.
- In case of payments through a third party, our payment date to the third party is used as the determining factor to allocate the payment to the related calendar year.

Our aim is to have an efficient and fast processing of payment data, but whilst we update our systems, payment information could sometimes become available only after the date of publishing. We are striving to improve this situation and will monitor actual occurrences.

How do we report ToVs related to multi-year contracts?

- In these cases, we use a split payment approach, so the total value is transferred in multiple, separate payments over time.
- Each of these separate payments will be included in the calendar year in which we executed the actual payment or reimbursement in our financial systems.

Is VAT included?

- All payments (e.g., Fees for Service, Donations, Grants, Sponsorships and other financial support), are reported exclusive of VAT.
- All ToVs from services or products (e.g., flight ticket, hotel room etc.) are reported gross, so inclusive of VAT where it is applicable.

How are different currencies handled?

- All values reported are in local currency, i.e., the currency of the country in which disclosure is made.
- For ToVs that were originally made in non-local currency, a conversion to local currency is made and exchange rate details can be provided on a case-by-case basis.

What is reported in case of partial meeting attendance/cancellation?

- Only costs related to the partial participation are reported. Costs of cancellation prior the event are not reported as they do not constitute a value transfer to its recipients.

Shionogi Europe - Methodological Notes

What is reported in case the TOV is made to/through a third party?

In case an HCP is contracted and paid through an HCO (Health Care Organization) that the HCP is part of, we will disclose the TOV (Service Fee) on the HCO that received the TOV, subject to local code differences.

What is included in the aggregate disclosure section of the ABPI reporting template? (For countries where consent is required)

- The HCP's aggregate section of the Disclosure reporting template contains the total value per cost type that was transferred to HCPs that have chosen not to be disclosed individually.
- According to individual privacy rights, consent to individual disclosure can be withdrawn by HCPs, in which case disclosure is made on an aggregate basis. We apply Consent or withdrawal of consent per HCP for all TOV on a per-activity basis
- Partial Consent: As Shionogi collects consent on a per-activity basis. Where recipients of transfers of value have decided to disclose as an individual in some activities and aggregate in others, the amount attributable to all transfers is disclosed on an aggregate basis.

What address do we show in the EFPIA report?

We will display the HCP/HCO/PO address available in our contract with HCP/HCO/POs that we have in our database at the time of the reporting.

How do we report R&D-related TOV?

- Shionogi reimburses CROs for payments they make to HCPs participating in clinical trials. Payments to such HCPs resident in the UK, have been reported in aggregate under the R&D heading.
- A third-party supplier made payments on behalf of Shionogi to HCPs in connection with their participation in investigator meetings to plan for clinical trials. These payments are disclosed in aggregate under the R&D heading.
- Thus, we report by country and as one annual total amount in aggregate basis, for all R&D ToVs to HCPs/HCOs
- R&D TOVs are TOVs to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Directive 2001/20/EC); or (iii) non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study
- Non-interventional retrospective studies are reported in HCO individual section of the report.

Cross Border Payments:

Shionogi operates in many countries and therefore may contract HCPs from different countries to perform services in other markets. Disclosure of these ToVs will be made in the recipient's home country. 'Home' country refers to the country where the recipient has its primary place of practice or registration. Similarly, payments made to local HCOs by Shionogi entities located in other countries are disclosed locally regardless of the source of funding.

Shionogi Europe - Methodological Notes

What to do if you have identified an error in your ToV(s) disclosed by Shionogi?

Please contact us via loveurope@shionogi.eu to request review and correction.

Disclaimer:

We rely on a manual data entry from internal and external resources to record relevant data and finally report it. The information reported in this submission reflects our good faith and best efforts to comply with the requirements of the EFPIA Code, but we are striving to improve using automated systems and standardised processes. Should we, despite our best efforts to ensure accurate reporting, fail to include complete and correct information in our submission, we will appropriately investigate and address in case of erroneous information.