

Janssen disclosure methodology for 2023

1. Introduction

The information below describes the methodology that Janssen Sciences Ireland UC (Janssen) has applied to disclose the Transfers of Value (ToV) made to Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs), in the submission to the Irish Pharmaceutical Healthcare Association (IPHA) for 2023.

2. Which payments will be disclosed?

The following types of payments to identified HCPs (as defined in clause 1.3 of the IPHA Code of Practice for the Pharmaceutical Industry) are disclosed:

- **Fees for services (FFS)**: Any payment made directly or indirectly via a third party acting on behalf of Janssen, to an individual for services provided by that individual which includes for example speaking or chairing an event on behalf of Janssen, participation at advisory board meetings and any other type of consultancy services.
- **Travel and accommodation costs related to FFS activity**: Any travel or accommodation costs booked by Janssen or a Janssen third party agent including any out of pocket expense claim processed to attend an event.
- **Support to attend an event**: This includes registration fees, travel or accommodation expenses booked by Janssen or a third party acting on behalf of Janssen, or an out of pocket expense claimed in relation to the attendance to the event.
- **Fee For service payments made to an individual as part of real-world evidence (RWE) research agreements**: Providing the research agreement relates to a defined non-interventional study that is retrospective in nature and where a fee for service has been paid directly by Janssen or indirectly via a third party acting on behalf of Janssen.

The following types of payments to identified HCOs (as defined in annex 5 of the IPHA code of practice) are disclosed:

- **Donations and grants**: The disclosure of donations and grants have been reported by the value that has been transferred either by a direct payment or indirectly by goods or services provided and where payment or goods or services have been made or delivered in 2023. Please see “How does Janssen report non-monetary ToV for benefits in kind made to Healthcare Organisations?” for further details.
- **Sponsorship, including contributions towards the costs of meetings**: Sponsorships paid directly to HCOs and Professional Conference Organisers are reported either in

the name of the benefitting HCO (where known) or in the name of the recipient Professional Conference Organiser.

- **Fees and expenses paid for contracted services:** In accordance with Annex 5 of the IPHA code of Practice, where there are contracts between companies and institutions, organisations or associations of HCPs.
- **Fee for service payments made to an organisation as part of RWE research agreements:** Provided that the research agreement has been defined as a non-interventional study that is retrospective in nature and where a fee for service has been paid directly by Janssen or indirectly via a third party.

3. What rules have Janssen applied to be included for disclosure?

The following rules apply:

- FFS costs to HCPs, (including HCPs who have retired since the ToV transaction was received) Donations, Grants and Sponsorships to HCOs and any other activities where a direct payment has been made, will be included in the calendar year in which Janssen executed the payment or reimbursement in our financial systems.
- ToVs related to travel (e.g. flight tickets etc.), accommodation (e.g. hotel room cost), registration fees and reimbursements for out of pocket costs, will be included in the calendar year during which the activity/meeting took place.
- In cases of payments through a third party acting on behalf of Janssen, our payment date to the third party is used as the determining factor to allocate the payment to the related calendar year.
- Other requests made by organisations such as learned societies, where a payment has been made to fund national conferences for the education of HCPs have been included in the disclosure report. This includes, for example, sponsorship towards professional conferences or sponsorship to the association's/society's annual conferences, where HCP education is the focus.

4. How is consent managed for individual public disclosure?

Janssen discloses ToV on the basis of legitimate interest. This means Janssen will no longer seek consent for individual Disclosure of ToV and will disclose annually any payments made by Janssen to recipients on an individual basis.

This change reflects Janssen's ongoing commitment to transparency, however if a recipient wishes to object to Janssen making the Disclosure on an individual basis, they can do so by emailing disclosure@janssen.ie.

HCOs cannot withdraw their consent and therefore all interactions are included.

5. What has Janssen excluded from the ToV Report?

- Charitable donations and payments made to patient organisations.
- Market Research projects, Janssen will only disclose ToVs to individuals where Janssen knows the

- identity of the individual participant.
- Payments made directly to medical journals or publishing companies.
- Ordinary course purchases and sales of medicines by and between a company and an HCP and HCO.
- Third-party events management companies which are not owned or run by HCPs these are not defined as HCOs. However, if the events company is a secretariat for an association or learned society which are in scope for an HCO, the learned society/association has been disclosed in place of the third party.
- Individuals or organisations that have been contracted by third parties unless the third party (i) is required to disclose such information to Janssen; and (ii) has, in fact, made Janssen aware of the individuals or organisation and their ToV, in which case Janssen has included these ToVs in the disclosure report.
- Direct costs towards food and drinks to individuals. However please note that some catering costs have been disclosed where costs for catering have been invoiced and charged for certain activities e.g. sponsorships with HCOs or breakfast costs with hotel room rates.

6. What about related expenses agreed in the FFS or consultancy contract?

If a HCP performed a service or provided consultancy, the related cost of travel, accommodation arrangements and any reimbursement of out of pocket expenses as per the contract terms, are reported in the designated report section in the disclosure report (i.e. “Related expenses agreed in the fee for service or consultancy contract”).

7. What is reported in cases of partial attendance/cancellation?

- Cancellation Fees are not reported.
- ToV in case of partial attendance is disclosed. For example, if a HCP was only able to attend two of the three planned days of an event; the accommodation costs for those two days will be reported.

8. What is reported when the hotel room rate is inclusive of breakfast cost?

Janssen has included the full hotel room rate as a cost for accommodation in the Disclosure report.

9. What is reported in cases where the ToV is made to/through a third party on behalf on an individual?

If a HCP contracts with Janssen through a private limited company and if any ToV is paid to the company in place of the HCP Janssen will attribute the ToV to the individual HCP and not the private limited company. In the case of the individual deciding to withdraw consent or object to Legitimate Interest, all payments instructed as above will be disclosed in the aggregate HCP section.

If a HCP contracts with Janssen and if a ToV is paid to their HCO that the HCP is employed by, Janssen will attribute the ToV to the HCO that received the ToV and not the HCP.

Any individual expenses, like travel & accommodation, will be reported and attributed to the HCP unless otherwise stated in the contract or if the individual objects to Legitimate Interest these will be disclosed in the HCP aggregate section.

If an individual HCP has been paid indirectly for a FFS by Janssen, for example through a HCO or other third party sponsored by or acting on behalf of Janssen, Janssen has attributed the ToVs to the individual HCPs when their details have been provided by the third party or HCO.

10. What is included in the aggregate disclosure section of the reporting template?

- HCP's aggregate section of the Disclosure reporting template contains the total value per cost type paid to HCPs that have chosen to object to Legitimate Interest Disclosure.
- According to individual privacy rights, objection to Legitimate Interest disclosure by HCPs is made on an anonymous aggregate basis. Janssen apply objection to Legitimate Interest per HCP for all ToVs for a given calendar reporting year.
- Individual HCPs can object to Legitimate Interest by emailing disclosure@janssen.ie
- Research and Development (R&D) payments are also included in aggregate, within the R&D category. Please see "Research & Development (R&D) ToV reporting" for further details on what is included in R&D.

11. What address is shown in the IPHA report?

Janssen will report the HCP or HCO address in the Janssen database at the time of reporting. If no current address is available within the database, Janssen will disclose the address the contract at the time the ToV took place or registered for a given activity.

Janssen has reported OneKey reference numbers as assigned by IQVIA who manage the Customer Relationship Management (CRM) system to the IPHA to help aggregate individual HCPs ToV with those of other companies.

12. How does Janssen report non-monetary value for ToV for benefits in kind made to HCOs?

Janssen discloses benefits in kind using the fair market value listed in the contract between Janssen and the HCO.

13. How does Janssen report ToV related to multi-year contracts?

For contracts that span multiple years, typically a split payment approach is used. This means that the total value is transferred in separate payments over time.

Each of these separate payments will be included in Janssen disclosure numbers for the calendar year in which Janssen executed the actual payment or reimbursement in our financial systems.

14. What is included in contributions to costs of meetings?

Janssen has disclosed any sponsorship contribution made to an HCO or a third party to organise an event on behalf of an HCO, including costs for stand space rental and symposiums.

This may sometimes include catering costs where charged.

If a payment is requested by an HCO which has contracted a third party to manage an event on their behalf, Janssen has disclosed the ToV associated to the HCO if known, irrespective of whether the payment is made to the HCO or to the third party.

15. VAT & Withholding Tax

Direct payments are disclosed exclusive of VAT and inclusive of withholding tax, if applicable. All ToVs for travel and accommodation (e.g. flight ticket, hotel room, etc.) are reported inclusive of VAT where applicable.

The disclosure reported ToV amounts should not be used for VAT/Tax reporting purposes. If fiscal reports are required, the company provides them directly to the HCPs or HCOs.

16. How are different currencies handled?

All values reported are in Euro.

For ToVs that were originally paid in a different currency, a conversion to local currency is made. Exchange rate details can be provided on a case-by-case basis.

17. Which Janssen companies have a duty to disclose ToVs?

Janssen is a member of the IPHA. Janssen has a code requirement to disclose all ToVs made to HCPs or HCOs based in Ireland by:

- Janssen; or
- Any European Janssen foreign affiliate company. This includes any cross-border interactions with Janssen in Europe where payments have been made to Irish based HCPs or HCOs; these have been included in the Irish disclosure report; or
- Any other global affiliate of Janssen.

J&J Consumer and J&J Medical device companies are not part of Janssen and therefore are not included in the disclosure.

18. Research & Development (R&D) ToV reporting

Research & Development (R&D) ToVs to HCPs or HCOs that have been disclosed in aggregate are related to the planning or conduct of:

1. Non-clinical studies (as defined in the OECD Principles of Good Laboratory Practice)
2. Clinical trials (as defined in Directive 2001/20/EC)
3. Non-interventional studies that are prospective in nature and involve the collection of data from, or on behalf of, individual or groups of health professionals specifically for the study.

Janssen has reported R&D ToVs as one annual total amount for Ireland which includes all R&D TOVs to HCPs/HCOs. This is aligned with the IPHA's disclosure requirements, and no individualised reporting for R&D TOVs has been disclosed, unless the study was deemed non-interventional and retrospective in nature.

19. Activities handled through distributors/sales intermediaries

ToVs by a distributor/sales intermediary NOT made on behalf of/at the direction of a J&J Company will be disclosed by the distributor/sales intermediary and not by the J&J Company.

Disclaimer

Janssen relies on a combination of automated systems, standardised processes, and manual data entry from internal and external resources to record and report relevant ToV data. The information reported in this submission is done in good faith and best efforts to comply with the requirements of the IPHA Disclosure Code. Although Janssen strive for efficient and fast processing, it might occur that payment information becomes available only after the date of publishing. 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. Janssen expect this to be exceptional and will monitor actual occurrences. In case of significant changes to the initial publication (e.g. withdrawal of consent for individual disclosure or objection to Legitimate Interest) Janssen will publish an amendment within a reasonable timeframe.

Should an HCP or HCO consider that the report is incomplete or incorrect, please contact us via disclosure@janssen.ie and we will make appropriate changes as soon as possible.

The information on ToVs is disclosed to the IPHA for the purpose of meeting IPHA reporting requirements. The payments disclosed should not be used as backup for tax declarations or other purpose.