

# Janssen Disclosure Methodology for 2021

## 1. Introduction

The information below describes the methodology that Janssen has applied to disclose the Transfers of Value (ToV) made to Healthcare Professionals (HCPs), Other Relevant Decision Makers (ORDMs) and Healthcare Organisations (HCOs), in the submission to the Association of British Pharmaceutical Industry (ABPI) for 2021.

Transfers of Value to Patient Organisations will continue to be disclosed on the Janssen public website ([www.janssen.com/uk/disclosure](http://www.janssen.com/uk/disclosure)).

## 2. Which payments will be disclosed?

The following types of payments to identified HCPs and ORDMs (as defined in Clause 1.9 and 1.13 of the 2021 ABPI Code of Practice and in addendum 1) are disclosed:

**Fees paid for contracted services:** In accordance with Clause 24.6 of the 2021 ABPI Code of Practice, 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 at or chairing an event on behalf of Janssen, participation at an advisory board meeting and any consultancy services.

**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.

**Expenses paid for contracted services:** In accordance with Clause 24.6 of the 2021 ABPI Code of Practice, any travel or accommodation costs booked via Janssen or a Janssen third party agent including any out-of-pocket expense claim processed to attend an event.

**Sponsorship to attend an event, including contributions toward the costs of meetings:** In accordance with Clause 10.10 of the 2021 ABPI Code of Practice, this includes registration fees, travel or accommodation booked via Janssen or a third party acting on behalf of Janssen, or an out-of-pocket expense claimed in relation to attendance at an event.

The following types of payments to identified HCOs (as defined in Clause 1.8 of the 2021 ABPI Code of Practice) are disclosed:

**Collaborative working, including joint working:** In accordance with Clause 20 of the 2021 ABPI Code of Practice, the disclosure of collaborative working, including joint working has 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 2021. This does not include payments made by Healthcare Organisations or other pharmaceutical companies. Specific details can be found on the Janssen public website ([www.janssen.co.uk](http://www.janssen.co.uk)). The information displayed on the website includes: the contracting parties, Janssen contributions, date the contract was signed, duration of the agreement and the description.

**Donations and grants:** In accordance with Clause 23 of the 2021 ABPI Code of Practice, the disclosure of donations and grants, including ongoing Medical Educational Goods & Services 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 2021. 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:** In accordance with Clause 10.11 of the 2021 ABPI Code of Practice, when paid directly to HCOs and Professional Conference Organisers. These ToV 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 Clause 24.6 of the 2021 ABPI 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:

- Fees paid for contracted services to HCPs/ORDMS (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 including reimbursements for out-of-pocket costs, will be included in the calendar year during which the activity/meeting took place.
- In cases of payments processed via a third party acting on behalf of Janssen, our payment date to the third party or the payment date provided by the third party is used as the determining factor to allocate the payment to the related calendar year.

### 4. How Janssen manages individual public disclosure?

Janssen disclose on the basis of legitimate interest. Where an HCP or ORDM has objected to disclosure on an individual basis, all associated ToV will be disclosed in the aggregate section of the report.

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

## 5. What has Janssen excluded from the Disclosure Report?

- ToVs to unknown identities e.g., market research.
- Ordinary course purchases and sales of medicines by and between a company and an HCP or HCO.
- Package deals solely related to ordinary course purchases and sales of medicines.
- Payments made directly to medical journals and publishing companies with the exception of grants funding.
- ToVs provided in accordance with Clauses 10.4, 10.5 & 19.2 of the ABPI Code of Practice.
- 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., breakfast costs with hotel room rates.
- 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).

## 6. What about related expenses agreed in the contracted service contract?

If an HCP/ORDM performed a contracted 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., “contracted services, expenses).

## 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 an HCP/ORDM attended 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 an HCP/ORDM contracts with Janssen through a private limited company and if any ToV is paid to the company in place of the HCP/ORDM, Janssen will attribute the ToV to the individual HCP/ORDM and not the private limited company. In the case of the individual deciding to object to legitimate interest disclosure, all payments instructed as above will be disclosed in the aggregate HCP section.

If an HCP/ORDM contracts with Janssen and the ToV is paid to the HCO that the HCP/ORDM is employed by, Janssen will attribute the ToV to the HCO that received the ToV and not the HCP/ORDM.

Any individual expenses, like travel & accommodation, will be reported and attributed to the HCP unless otherwise stated in the contract.

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

The HCP/ORDM aggregate section of the disclosure reporting template contains the total value per cost type paid to HCPs/ORDMs that have chosen to object to disclosure on an individual basis.

According to individual privacy rights, objection to a legitimate interest disclosure and consent to individual disclosure can be withdrawn by HCPs/ORDMs in which case, the disclosure is made on an anonymous aggregate

basis. Where an HCP or ORDM has objected to disclosure on an individual basis, all associated ToV will be disclosed in the aggregate section of the report.

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 ABPI report?**

Janssen will report the HCP/ORDM 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 on the contract at the time the ToV took place or the address provided at the time of registering for a given activity.

Janssen has reported OneKey reference numbers as assigned by iQVIA who manage the customer data for the Janssen Customer Relationship Management (CRM) system to the ABPI to help aggregate individual HCPs or ORDMs 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?**

Where contracts span multiple years, each individual ToV is captured and disclosed in the corresponding reporting period. This does not include payments from agreements that were made in 2014 or previous years which may span multiple years.

## **14. 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/ORDMS or HCOs.

## **15. How are different currencies handled?**

All values reported are in GBP.

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.

## **16. Which Janssen companies have a duty to disclose ToVs?**

Janssen Cilag Limited (Janssen UK) is a member of the ABPI. Janssen UK has a code requirement to disclose all ToVs made to HCPs/ORDMs, or HCOs based in the UK by:

- Janssen UK; or
- Any European affiliate company of Janssen UK; or
- Any other global affiliates of Janssen UK.

This includes any cross-border interactions where payments have been made to UK based HCPs/ORDMs or HCOs; these have been included in the UK disclosure report.

## 17. 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 Regulation 536/2014)
3. 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 health professionals specifically for the study.

Janssen has reported R&D ToVs as one annual total amount for the UK which includes all R&D TOVs to HCPs/HCOs. This is aligned with the ABPI'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.

## 18. Activities handled through distributors/sales intermediaries

ToVs by a distributor/sales intermediary which are 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 ABPI 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., objection to individual disclosure, Janssen will publish an amendment within a reasonable timeframe.

Should a HCP/ORDM or HCO consider that the report is incomplete or incorrect, please (1) contact us via [disclosure@janssen.co.uk](mailto:disclosure@janssen.co.uk); (2) as requested by the ABPI, please also make a request through the ABPI central database to ensure your query is captured and we will endeavor to make appropriate changes as soon as possible.

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

## Addendum 1

### ToV Decision Tree – HCPs & ORDMs

- Determine whether a HCP or ORDM should be reported for ToV.

