Janssen disclosure methodology for 2015

The information below describes the methodology that Janssen has used to disclose the Transfers of Value (ToV) we have made to Healthcare Professionals (HCPs), Other Relevant Decision Makers (ORDMs) and Healthcare Organisations (HCOs), to the Association of British Pharmaceutical Industry (ABPI) for 2015.

Which payments will be disclosed?

The following types of payments to identified HCPs and ORDMs (As defined in Clause 1.4 and 1.5 of the 2015 ABPI Code of Practice and in Addendum 1) are disclosed:

1. 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.
2. Travel and accommodation costs related to FFS activity: Any travel or accommodation costs booked via Janssen or a Janssen third party agent or an out of pocket expense claim processed in order to attend an event.
3. Sponsorship to attend an event: This includes registration fees, any travel or accommodation expenses booked via 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.
4. FFS payments made to an individual as part of Real World Evidence (RWE) research agreements: Providing that the research agreement relates to a study that is retrospective in nature and where a FFS has been paid directly by Janssen or indirectly via a third party acting on behalf of Janssen (these will be reported, only when Janssen has been made aware of the individual's identity).

The following types of payments to identified HCOs (as defined in Clause 1.9 of the 2015 ABPI Code of Practice) are disclosed:

1. Joint Working Initiatives (JWIs): In Accordance with Clause 20 of the 2015 ABPI Code. Please see "How are Joint Working Initiatives (JWIs) defined?" for further details.
2. Medical Education Goods and Services: Are the provision of good and services that enhance patient care, or benefit the healthcare system and maintain patient care. In accordance with Clauses 19.1 and 19.2 of the 2015 ABPI Code, which also include:
   a. Donations
   b. Grants
   c. Benefits in kind

   Please see "How does Janssen define Medical Educational Goods and Services?" and "How does Janssen report non-monetary ToV for Benefits in kind made to Healthcare Organisations (HCOs)?" for further details.
3. Contributions towards the costs of meetings: When paid directly to HCOs or paid to third parties managing events on the HCO's behalf.
4. FFS: Where there are contracts between companies and institutions, organisations and associations in accordance with Clause 21 of the 2015 ABPI Code.
5. FFS payments made to an organisation as part of RWE research agreements: Provided that the research agreement relates to a study that is retrospective in nature and where a FFS has been paid directly by Janssen or indirectly via a third party (these will be reported, only when Janssen has been made aware of the identity).

There is a further category for HCP/ORDM ToV disclosures, whose identities cannot be disclosed for legal reasons (for example if they have refused consent to disclosure) and where Janssen has therefore disclosed ToVs in this category on an aggregate basis. The aggregate disclosure includes the number of HCPs/ORDMs who have withdrawn their consent, the percentage of HCPs/ORDMs and the total amount paid. Please see "What is included in the aggregate disclosure section of the reporting template?" for further details.

Research and Development (R&D) ToV disclosures within the meaning of Clause 23.2 of the Code have also been disclosed on an aggregate basis.

What rules have Janssen applied to be included for disclosure?

As 2015 is the first year of disclosure, Janssen has included ToVs related to those events/activities that started as of, or after the 1st January 2015. Any ToV related to an event/activity that took place before 1st January 2015 will not be included.

The following rules apply:

- FFS costs to HCPs or ORDMs, 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 actual 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. Please note, the disclosure report does include some out of pocket costs which have been claimed in 2016 but are reported due to the event taking place in 2015.
- 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.

How does Janssen manage consent for individual public disclosure?

Janssen operates an automatic opt in for individual public disclosure. This means that by signing a contract and accepting a payment from Janssen directly, HCPs/ORDMs are opted in and the value of their payments will be disclosed. If a HCP/ORDM accepts travel and accommodation or has claimed for an out of pocket expense, this is also included as an automatic opt in.

Individual HCPs/ORDMs can withdraw their consent via a secure website managed by Janssen or they can contact Janssen directly. Details on how they can access this secure website have been provided to HCPs/ORDMs that have had a ToV with Janssen.

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

What has Janssen excluded from the ToV Report?

Janssen has excluded any charitable donation payments made to patient organisations and charities, as these payments will be covered by Clauses 27.7 and 27.8 of the 2015 ABPI Code. Janssen is reporting payments made to patient organisations and registered charities on the Janssen public website (www.janssen.co.uk).

Other requests made by registered charities, also known as learned societies, where a payment has been made to fund national conferences for the education of HCPs/ORDMs 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.

In relation to market research projects, Janssen will only disclose ToVs to individuals where Janssen knows the identity of the individual consultant. For 2015 no such disclosures have taken place.

Janssen has excluded any payments made directly to medical journals.

Janssen will not disclose individuals or organisations that have been contracted by third parties unless the third party has made Janssen aware of the individuals or organisation and their ToV. If known, Janssen have included these ToVs in the disclosure report.

Janssen has not disclosed any 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.

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

If a HCP/ORDM performed a service or provided consultancy, the related cost of travel, accommodation arrangements provided 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”).

What is reported in cases of partial attendance/cancellation?

In the event that a HCP/ORDM was unable to participate in an event or part of an event, only the costs that still constitute a true ToV to that HCP/ORDM have been included in the disclosure report.

For example, if a HCP/ORDM was only able to attend two of the three planned days of an event; the accommodation costs for those two days will be reported. Costs of cancellation prior to the event are not reported, as they do not constitute a ToV to the HCP/ORDM. Costs are also excluded from disclosure if a HCP/ORDM, for whatever reason, is unable to attend an event, as there has not been any true ToV to that HCP/ORDM.

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.

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

If a 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 withdrawn consent, all payments instructed as above will be disclosed in the aggregate HCP section.

If a HCP/ORDM contracts with Janssen and if any ToV is paid to their 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. In the case of the individual deciding to withdrawn consent, all payments instructed as above will be disclosed in the named HCO section, since HCOs cannot withdraw their consent.

In both of these situations, any individual expenses, like travel & accommodation, will be reported and attributed to the

HCP unless otherwise stated in the contract or if the individual withdraws consent these will be disclosed in the HCP aggregate section.

If an individual HCP/ORDM 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.

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

The HCP's/ORDM's aggregate section of the Disclosure reporting template contains the total value per cost type that was transferred to HCPs/ORDMs that have chosen to opt-out of individual disclosure.

According to individual privacy rights, consent to individual disclosure can be withdrawn by HCPs/ORDMs, in which case disclosure is made on an anonymous aggregate basis. Janssen apply consent or withdrawal of consent per HCP/ORDM for all ToVs for a given calendar reporting year.

Individual HCPs/ORDMs can withdraw their consent via a secure website managed by Janssen or by contacting Janssen directly. Details on how HCPs/ORDMs can access this secure website have been provided to HCPs/ORDMs that have had a ToV with Janssen.

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.

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 that was written within the contract at the time when the ToV took place or registered for a given activity.

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

How are Joint Working Initiatives (JWIs) defined?

Joint working initiatives (JWIs) between Janssen and the NHS, or other organisations, or with other pharmaceutical companies disclosed, are in accordance with clause 20 of the 2015 ABPI Code. JWIs disclosed also include work conducted though third party service providers and/or with suppliers of private healthcare where applicable.

When Janssen works with ABPI therapy groups, Janssen has disclosed the costs based on the information provided from the ABPI. If payments have been made to individuals, the information provided by the ABPI has been disclosed. The ABPI provide a breakdown of costs, which is then divided by the number of other pharmaceutical companies supporting the event, this divided amount is what Janssen has disclosed.

Janssen has only disclosed the payment made by Janssen for JWIs; this does not include any additional payments made by HCOs or other pharmaceutical companies.

The disclosure of JWIs has been reported by the value that has been transferred either directly by a direct payment or indirectly by services provided, where contracts are in place and payments or services have been made or delivered in 2015.

This does not include value transferred from agreements that were made in 2014 or previous years which may span multiple years. The disclosure also does not include JWIs that have been made between registered charities or patient organisations.

If a JWI relates to a multi-year contract starting from 2015, please see "How do Janssen report ToV related to multi-year contracts?"

Specific details on JWIs can be found on the Janssen public website (www.janssen.co.uk). The information outlined on the website includes: an outline of the agreement, Janssen contributions, date the contract was signed, duration of the agreement and the description.

How does Janssen define Medical and Educational Goods and Services (MEGS)?

Janssen has disclosed Medical and Educational Goods and Services (MEGS), including donations, grants and benefits in kind to institutions, HCOs or associations that consist of HCPs and/or provide healthcare or conduct research, in accordance with clause 19.1 of the 2015 ABPI code.

These are all documented by a contract and do not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine made by Janssen.

The disclosure of MEGS have been reported by the value that has been transferred either directly by a direct payment or indirectly by goods or services provided, where contracts are in place and payments or goods or services have been made or delivered in 2015.

This does not include value transferred from agreements that were made in 2014 or previous years which may span multiple years. The disclosure also does not include MEGs that have been made between registered charities or patient organisations.

If a MEGS relates to a multi-year contract starting from 2015, please see "How do Janssen report ToV related to multi-year contracts?"

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

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

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 particular calendar year in which Janssen executed the actual payment or reimbursement in our financial systems.

The payments disclosed are the value received by the given HCO for the calendar year of 2015. If the contract spans over to the following year, the remaining value will be reported within the next disclosure reporting year (e.g. 2016 onwards).

This does not include value transferred from agreements that were made in 2014 or previous years which may span multiple years.

What is included in contributions to costs of meetings?

Janssen has disclosed any sponsorship contribution made to a 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 irrespective of whether the payment is made to the HCO or to the third party.

Is VAT included?

All payments related to an individual HCP/ORDM (e.g. FFS, consultancy, etc.) are reported exclusive of VAT unless charged by the individual through their private consultancy company.

All payments related to an HCO (e.g. Donations, Grants, Sponsorships, Fees for Service, Consultancy, Joint Working Initiatives, etc.) are reported exclusive of VAT unless charged by the HCO.

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 any VAT/Tax reporting purposes. If fiscal reports are required, the company provides them directly to the HCPs/ORDMS or HCOs.

How are different currencies handled?

All values reported are in GBP.

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

Which Janssen companies have a duty to disclose ToVs?

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 Janssen foreign affiliate company; or
- Local Janssen ABPI based affiliates.

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

Are ToVs made by non-ABPI member based Johnson & Johnson (J&J) companies reported?

We have disclosed ToV to any HCP/ORDM or HCO based in the UK, regardless of which Janssen Company organised and/or made the ToV.

Activities as defined in scope for disclosure by the 2015 ABPI Code with Janssen Healthcare Innovation (JHI) are included within Janssen UK's disclosure.

Activities as defined in scope for disclosure by the 2015 ABPI Code which have taken place with Janssen companies outside of Europe have been included for disclosure e.g activities taken place in the United States are included.

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

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 the UK which included all the 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.

How has Janssen reported Real World Evidence studies that are retrospective non-interventional studies in nature?

Janssen has disclosed Real World Evidence research defined as a non-interventional study that is retrospective in nature, if payments were made to HCOs or individuals directly as a FFS on an individual named basis. Where payments have been made to an HCO or HCP/ORDM via a third party/vendor, Janssen has reported these as a FFS only when Janssen has been made aware of who has received the ToV.

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.

Where will ToV data be published?

In the UK, details of ToV will be submitted by pharmaceutical companies and published on a central platform, accessible via the ABPI website. Data will be publicly searchable by a number of criteria including individual HCO, geographic area, pharmaceutical company and activity type.

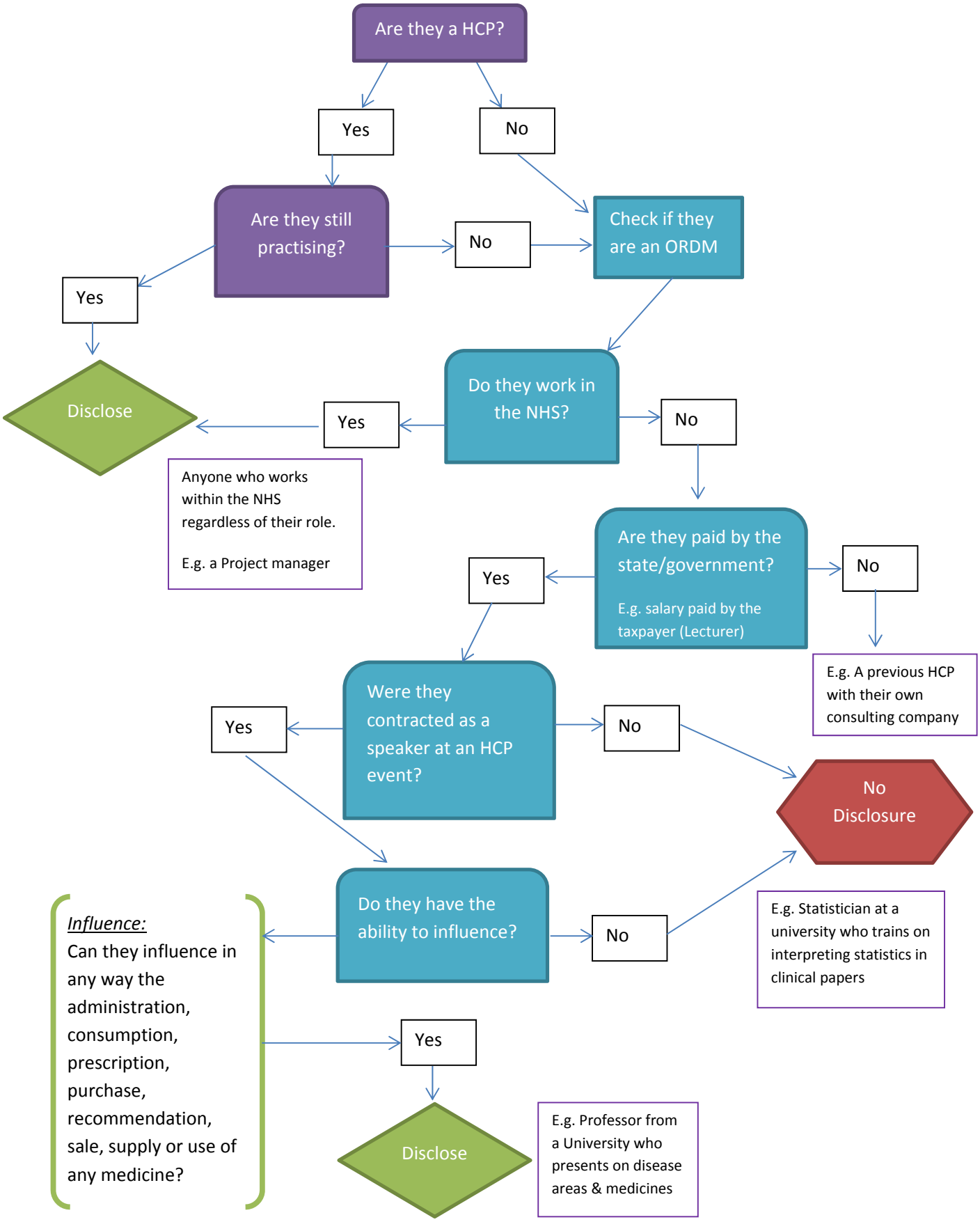
The Janssen UK (www.janssen.co.uk) public website will host a link to where the information will be published.

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. withdrawal of consent for individual disclosure) Janssen will publish an amendment within a reasonable timeframe.

Should an HCP/ORDM or HCO consider that the report is incomplete or incorrect, please contact us via disclosure@janssen.co.uk, please also as requested by the ABPI make a request through the ABPI central database to ensure your query is captured and we will endeavour 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 as backup for tax declarations or other purposes.

Addendum 1 - ToV Decision Tree – HCPs & ORDMs

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