

Methodological Note for 2019 Disclosure

Methodological Note explaining the implementation of the European Federation of Pharmaceutical Industries and Associations (EFPIA) Disclosure Code, in accordance with the Association of the British Pharmaceutical Industry (ABPI) Code of Practice.

Disclosure period: Calendar Year 2019

July 2020

Vifor Pharma Group (VPG) are committed to transparency regarding how Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs) are paid by or receive a benefit in kind from VPG for the time and expertise they provide. When collaborating with medical experts, we comply with all applicable laws, regulations and codes of practice, such as the EFPIA Disclosure Code in Europe, and various local legal reporting obligations fully respecting the independence and integrity of these professionals.

In the UK, the ABPI Code of Practice incorporates the requirements of the EFPIA Disclosure Code. The ABPI Code requires that all transfers of value (ToV) made by companies in connection with joint working between the NHS and pharmaceutical industry must be publicly disclosed.

VPG provides medical and educational goods and services (MEGS) in the form of services, donations, and grants to organisations or associations that comprise health professionals and/or that conduct research. MEGS provided by VPG to HCOs are made for the purpose of enhancing patient care or to benefit the NHS in maintaining patient care.

The purpose of this methodology note is to allow any person accessing the report to understand how VPG is documenting and disclosing the relevant information. In particular, it will explain the details of the data collection and how these data are reported. The general rules of the EFPIA Disclosure Code apply to all member companies and all companies will disclose relevant ToV in a pre-defined format. However, some details of the reporting methodology are left for the individual companies to decide in order to allow the necessary flexibility to adjust for internal company processes.

If in doubt about the duty to disclose a specific ToV, VPG will always aim for full disclosure. Only if a ToV is clearly out of scope of the Disclosure Code, will it not be included in the published report.

Commitment to transparency

In-line with guidance provided by the ABPI, Vifor Pharma Group's 2019 transfer of value data was published on Disclosure UK in aggregate and disaggregated data for Healthcare Organisations was published on VPUK's website at the link below

<https://www.viforpharma.com/en/about-vifor-pharma/transparency/healthcare-professionals-and-organisation/2019>

1. General Summary

This disclosure includes all ToV made by the Vifor Pharma Group (VPG) to Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs), either directly or indirectly during 2019. The Vifor Pharma Group is comprised of two companies, Vifor Pharma UK Limited (VPUK) and Vifor Fresenius Medical Care Renal Pharma Limited UK (VFMCRPUK).

The company named Fresenius Medical Care UK Limited is not part of the VPG.

2. Data Privacy and Consent Management

As the Disclosure Code is a voluntary self-obligation of the pharmaceutical industry, publication of data is dependent on the consent of the HCP concerned. Every individual under GDPR and the DPA is entitled to protection of data relating to them. This basic right covers the recording, processing and dissemination of any personal information, whereby any of these shall require the specific consent of the person affected. There are strict requirements for any such consent – it must be explicit, it needs to be visually highlighted in any contractual texts or similar documents and must be clearly and transparently worded.

- VPG chooses to work with all HCPs, regardless of whether or not they give their consent to disclose.
- VPG requests consent from all HCPs before declaring a ToV to the individual concerned. If individual consent is not granted, VPG will only publish the ToV in the aggregated section of the report; VPG will not specify the name, address or other personal data of the recipient.
- Where VPG have not received a response on the issue of consent it will be assumed that consent is not given and so all ToV will be included in the aggregated section.
- VPG has obtained consent once, not for each activity and for the majority of HCPs this has been given at the same time as contracts signed for the initial activity undertaken with VPG.
- Consent is total, it is either given and full declarations are made for all activities, or it is not and all activities are entered into the aggregated section.
- Change of consent:
 - Withdrawal of consent:
 - If a HCP wishes to withdraw consent for a particular activity, then consent will be withdrawn for all activities and that total will be included in the aggregated amounts. Any activity from previous years will remain in the published amounts, unless the HCP specifically requests that all publically visible ToV are withdrawn.
 - Consent now given
 - If a HCP decides to give consent then activity from that year on shall be disclosed. Any activity from previous years will be left in the aggregated amounts.

3. Financial considerations

- Currency conversions are taken at the point of transfer. Where this has been unavailable and conversions have been required, exchange rates have been sourced from xe.com and recorded
- Publication of ToV granted in a foreign currency is applicable when the monetary contribution was made in a different currency to the local currency of the recipient country.

Examples:

A HCP based in Spain receives funding from VPG to take part in a scientific and educational event in the UK and the registration fee is paid in sterling.

VFG would convert the reimbursement of the registration fee to euros and the ToV declared by the Spanish VPG affiliate.

A HCP registered to practice in the UK is acting as a speaker for an event in Germany. The flight is booked by our German affiliate and is paid in Euros.

VPG would convert the costs of the flight into sterling and the ToV would be declared by VPG in the UK as this is where the recipient is registered to practice.

- VAT is applicable where VAT has been paid. The ToV will be calculated based on the actual amount received by the recipient, either in kind or in cash.

4. Criteria for inclusion/exclusion

- The disclosures include no more than is required by the ABPI Code.
- Information declared includes ToV that have actually been made, they exclude any planned transfers which HCPs do not complete for whatever reason.
- ToV are declared according to the year in which the actual payment or transfer takes place
 - Work undertaken in the previous year but paid in the current year will be declared in the current year
 - Planned transfers may be accrued into the following year and, if made in the following year, will be declared as a transfer in that year
 - If an agreement covers payments over several years, then each payment will be declared according to the year in which it is actually made
- ToV include those made by global VPG affiliates to UK HCPs.
- No over-the-counter medicines which are subject to a marketing authorisation or traditional herbal medicines registration ToV have been included.

5. Service and Consultancy Fees

- Under the category 'service and consultancy fees', VPG record any ToV (monetary or a benefit in kind), which is granted in exchange for services provided by an HCP or HCO. Services provided by experts will be remunerated at fair market value. Generally, fees for services are honoraria paid for services like speaker engagements or a consultancy.
- In terms of ToV falling under the category "service and consultancy fees", the data record template provides for any expenses reimbursed being published in addition to and separately from the fee itself. These expenses generally include travel and accommodation costs.

6. Expenses Related to Travel & Accommodation

- VPG will disclose any travel and accommodation costs for HCPs and HCOs that are not related to services as depicted above or R&D activities in this category. This includes, for example, costs for flights, train, taxi and hotel costs (including daily delegate rates).
- If travel is organised through an external travel agency or 3rd Party, the administrative costs of that travel agency will not be reported only the ToV that has actually been provided to individual participants.
- Continuous Professional Development (CPD) internal events are defined as events organised by VPG itself. VPG does not charge registration fees for its own events. On the occasion that VPG have paid travel and or accommodation costs for those persons attending our internal events, details of such will be published specifying the name of the relevant HCP in the category provided for this purpose.

7. Registration Fees

- VPG will publish the payment of registration fees as a ToV to the relevant HCPs in the section devoted to "registration fees". The total amount of such fees assumed during the reporting period will be published for each individual HCP. Such fees can also be reported for a HCO, e.g. if VPG supports the participation of a certain number of physicians working at a hospital and the hospital chooses the participants. In such case, the hospital is seen as the recipient of the ToV.

8. Donations and Grants to HCOs

- In the event that the donation is clearly intended for a specific department or unit within a hospital and this department is a legal entity in its own right, we will publish details of the donation and give the name of the department. In the event that the donation is made to the hospital as a whole, or if the department is not a legal entity we will publish the donation under the name of the hospital or trust.

9. Transfers of Value Related to Contribution to Costs of Events

- Events are defined as promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including but not limited to advisory board meetings, visits to research or manufacturing facilities, and planning, training or conducting of investigator meetings for clinical trials and non-interventional studies) organised or supported by or on behalf of VPG pursuant to schedule 1 of the EFPIA Disclosure Code.
- ToV to participating HCPs/HCOs related to such events falling under the definition above are disclosed in the “Costs of Events” sub-categories “Sponsorship Agreements”,
- “Registration Fees” or “Travel and Accommodation”. ToV made through a conference organiser as an intermediary e.g. for the hire of booths or stand space on behalf of a HCO, are disclosed as ToV under the “Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event” category. In the interests of transparency, payments that have been made directly to meeting venues for stand meetings have been disclosed against the HCO beneficiary name.

10. Research & Development (R&D)

- For the purpose of disclosure, R&D ToV are made to HCPs or HCOs and related to the planning or conduct of non-clinical studies (as defined in the OECD Principles of Good Laboratory Practice); clinical trials (as defined in Directive 2001/20/EC); non-interventional studies that are prospective in nature and involve the collection of data from, or on behalf of, individual or groups of HCPs specifically for the study. Costs that are subsidiary to these activities can be included in the aggregated area.

11. Other general points

- Where MEGS have been provided to HCOs, the relevant cost of the goods and services have been disclosed under the ‘Donations and Grants’ category.
- Fully sponsored delegates come under the category of ‘Sponsorship of attendance by HCPs at meetings’
- Where a HCP has benefitted from ‘free’ registration to a third party meeting where VPG has not borne any direct cost for that registration (for instance when VPG has given a HCP a registration pass that has come as part of a sponsorship package), the value attributed to that pass that has been allied to the HCP is disclosed as a ToV at the standard entry cost.
- Transfers of value made within the course of any package related deals will be disclosed in accordance with the relevant services of HCPs as outlined above.
- Recording of ToV granted to universities and other educational establishments:
 - Universities and other educational establishments or organisations are not ‘usually’ in scope of the EFPIA Disclosure Code. VPG will however publish details of such ToV in the event that they are considered an indirect ToV to a HCO, such as a university hospital, or one or more HCPs. In such cases, we will publish the details of each of those ToV under the name of the university or other educational establishment to which they were granted.
- Where funding has been requested by a Patient Organisation and subsequently support has been provided then the VFG will make publicly available, at the European level, a list of patient organisations to which we have provided financial support and/or significant indirect/non-financial support, which includes a description of the nature and significance of the support. The list of organisations is disclosed annually within the first six months after the end of the calendar year in which the transfers of value were made.

Any questions on the content within this document should be referred to the Medical Compliance Officer, Vifor Pharma UK, via email abpicompliance@viforpharma.com