

Chiesi Ltd: Methodological note for disclosure of Transfers of Value for 2018

Introduction

The Association of British Pharmaceutical Industry (ABPI) Code of Practice requires that all companies must document and publically disclose certain transfers of value made directly or indirectly to health professionals, other relevant decision makers (ORDM) and healthcare organisations and patient organisations located in Europe. Disclosure is required even if the payments etc. are made by overseas affiliates, head offices in the UK or overseas and UK based offices. Each company providing transfers of value must publish a note summarising the methodologies used by it in preparing the disclosures and identifying each category of transfer of value.

Data Privacy law requires that Chiesi Ltd, based in the UK, obtains permission from individual health professionals/ORDMs prior to disclosing personal data such as individual transfers of value. Where permission has not been obtained or where the individual health professional/ORDM has refused permission, Chiesi has declared the total spend as an aggregate figure as a separate line entry within the required disclosure section.

About Chiesi:

As with every part of the Chiesi group, we embrace a shared set of values and a common code of ethical conduct. This demands the highest standards of reliability, transparency, and individual accountability, in everything we do, and emphasises the importance of collaborative working, putting people first and exchanging knowledge. Implicit in all of these is a responsible attitude to the social and environmental impact of our actions.

Definitions:

The term **'transfers of value'** means a direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines.

- A direct transfer of value is one made directly by Chiesi for the benefit of a recipient.
- An indirect transfer of value is one made on behalf of Chiesi for the benefit of a recipient or through an intermediary and where Chiesi knows or can identify the recipient that will benefit from the transfer of value.

The term **'health professional'** (HP) includes members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine. In relation to disclosure of transfers of value it also includes any employee of Chiesi whose primary occupation is that of a practising health professional.

The term **'other relevant decision makers'** (ORDM) particularly includes those with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who are not health professionals.

The term **'healthcare organisation'** means either a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in Europe or an organisation through which one or more HPs or ORDMs provide services.

The term **'registration fee'** refers to a fee paid to register, enroll or sign up for a formal training course or meeting or direct funding such as sponsorship fees.

The term **'travel and accommodation'** means the costs of travel and accommodation, both inside and outside the UK (this excludes subsistence payments).

The term **'expenses'** means the cost of any expenditure as a result of providing a service to Chiesi or attending an event where Chiesi has provided attendance support.

The term **'joint working'** means a situation where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to a successful delivery.

The term **'sponsorship'** means either the provision of support for a HP/ORDM to attend a medical/educational congress or the provision of money by Chiesi which is non-promotional and unconditional in nature given to facilitate a medical/educational meeting or service with no involvement from Chiesi. This also includes the purchase of exhibition stand space and/or the facilitation of a medical/educational meeting with Chiesi involvement.

The term **'Grant/Donation'** means a grant/donation of money in a wider area in which Chiesi has a clinical interest, such as a grant/donation to support the overall aims of establishing an independent asthma educational service.

Descriptors

1. Time period

- This Methodological Note represents disclosures for transfers of value in 2018. This means that any payment made in 2018 has been included in the disclosure irrespective of the commencement date of the service.
- Disclosures must be made annually in respect of each calendar year. Disclosure will be in the first six months after the end of the calendar year in which the transfers of value were made. The information disclosed will remain in the public domain for at least three years from the time of disclosure.

2. UK Data Privacy consent

- Individual HP/ORDM consent to publically disclose payments made to them has been obtained on a 'per activity' basis.
- If an individual HP/ORDM received a number of transfers of value from Chiesi and decided not to agree to disclosure of one or more of those transfers of value, then Chiesi has disclosed all transfers of value to that individual in the aggregate amount. Where permission has not been obtained the assumption has been made of "No" to consent. This means Chiesi has taken an all opt-in or all opt-out consent to disclose.
- HPs/ORDMs may at any time withdraw their consent and this will therefore mean that Chiesi will be required to report this data within the aggregate figure.

3. Tax considerations

- All payments reported do not have any provision for Personal or Corporation Tax paid by HPs/ORDMs and healthcare organisations.

4. VAT

- Payments made to HPs/ORDMs for either the fee for service, or expenses in relation to this service, are all exclusive of VAT.
- Payments made to healthcare organisations are reported inclusive and exclusive of VAT.
- Any sponsorship payments made to healthcare organisations are inclusive and exclusive of VAT.

5. Currency aspects (including conversion rates)

- Where a fee for service payment was agreed in Euros and paid in GBP with a HP/ORDM, the amount is then converted into GBP (using the exchange rate) at the time of contracting.
- Where a fee for service payment was agreed in Euros and paid in EUROS with a HP/ORDM, the amount is then converted into GBP (using the exchange rate) at the time of the event.

6. Research & Development

- The figure that Chiesi UK has provided refers to Research & Development which occurred in the UK and was paid directly by the UK. Full Chiesi Farmaceutici s.p.A global spend on Research & Development is disclosed on the Chiesi Italy EFPIA disclosure platform.

7. Cross border payments

- Payments to HPs/ORDMs and healthcare organisations in Northern Ireland are disclosed within the UK data platform.

8. Payments to healthcare organisations

- Payments to healthcare organisations are disclosed on a 'per activity' basis
- Payments to healthcare organisations in respect of stand space may be inclusive of food and beverages.

9. Payments to HPs/ORDMs

- Payments include transfers of value made directly or indirectly to HPs/ORDMs and include the total amount paid in a calendar year to each individual who has provided services.
- The names of the HPs/ORDMs are disclosed unless disclosure on a named basis has been declined. Where permission has not been obtained or where the individual HP/ORDM has refused permission, Chiesi has declared the total spend as an aggregate figure as a separate line entry within the required disclosure section.
- Where transfers of value are not individually identifiable, such as group cost, then the total amount will be apportioned equally between all those HPs/ORDMs who were the beneficiary of the support.

10. Unincorporated healthcare organisations

- Where Chiesi has provided financial support for educational meetings run and organised by groups of HPs/ORDMs who form educational healthcare organisations that do not have an official registered address in the UK, the total spend has been split equally between the total number of attendees and the value and number of recipients have been included in the aggregate for HCPs.

11. Name matching (from multiple sources)

- In those circumstances where no first name has been provided, i.e. only an initial, yet another entry may appear to be the same individual, Chiesi has disclosed this as two separate entries.
- In those circumstances where the first name, surname, place of work and address are the same, this has been assumed to be the same person.

12. Joint working

- Chiesi has not undertaken any Joint Working activity during 2018.

13. Aggregate figures

- The provision of aggregate data, where relevant, has been calculated by assuming the percentage cell for each column of category of spend is a percentage of the total number of individuals in both aggregate and disaggregate across all types of spend.