Chiesi Ltd.: Methodological note for disclosure of Transfers of Value for 2022

Introduction

The Association of British Pharmaceutical Industry (ABPI) Code of Practice requires that all companies must document and publicly 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.

Due to Data Privacy law, Chiesi Ltd, based in the UK, began to rely in the reporting period on the lawful basis of legitimate interest in order to process personal data in respect of individual transfers of value. Under this lawful basis, individuals were entitled to object to the processing of their personal data for this purpose. In the event of any objection which, after consideration by Chiesi, was successful, Chiesi has declared the total spend as an aggregate figure as a separate line entry within the required disclosure section. Some transfers of value in 2022 were in respect of contracts entered into in 2021 at which time Chiesi still relied on the lawful basis of consent. For those transfers of value, where consent has not been obtained or where the individual refused to provide consent, Chiesi has declared the total spend as an aggregate figure as a separate line entry within the required disclosure action.

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 practicing 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, enrol 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 'collaborative working' means a situation where, pharmaceutical companies work with other organisations to deliver initiatives which either enhance patient care or are for the benefit of patients or alternatively benefit the National Health Service (NHS) and, as a minimum, maintain patient care.

The term 'support' for an individual, means the provision of a financial contribution, in whole or in part, whether paid directly or indirectly to individual health professionals or other relevant decision makers to attend events/ meetings.

The term 'sponsorship' means a contribution, financial or otherwise, in whole or in part provided by or on behalf of a company towards an activity (including an event/meeting or material) performed, organised, created, etc., by a healthcare organisation, patient organisation or other independent organisation.

The term 'Grant/Donation' means a grant/donation of funds, benefits-in-kind or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient organisation, institution and the like to provide goods or services to the benefit of the pharmaceutical company in return.

Descriptors:

1. Time period

- o This Methodological Note represents disclosures for transfers of value in 2022. This means that any payment made in 2022 has been included in the disclosure irrespective of the commencement date of the service.
- o 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

- o Individual HP/ORDM payments have been disclosed against those individuals using the lawful basis of legitimate interest.
- Due to Data Privacy law, Chiesi Ltd, based in the UK, began to rely in the reporting period on the lawful basis of legitimate interest in order to process personal data in respect of individual transfers of value. Under this lawful basis, individuals were entitled to object to the processing of their personal data for this purpose. In the event of any objection which, after consideration by Chiesi, was successful, Chiesi has declared the total spend as an aggregate figure as a separate line entry within the required disclosure section. Some transfers of value in 2022 were in respect of contracts entered into in 2021 at which time Chiesi still relied on the lawful basis of consent. For those transfers of value, where consent has not been obtained or where the individual refused to provide consent, Chiesi has declared the total spend as an aggregate figure as a separate line entry within the required disclosure action Individual HP/ORDM payments have been disclosed against those individuals using the lawful basis of legitimate interest.
 - o 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

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

4. VAT

- o Payments made to HPs/ORDMs for the fee for service are all exclusive of VAT.
- O Payments made to HPs/ ORDMs for expenses in relation to service are inclusive and exclusive of VAT.
- o Payments made to healthcare organisations are reported exclusive of VAT.

5. Currency aspects (including conversion rates)

- o For fee for service payment paid in Euros, the amount is converted into GBP using the European Central Banks closing exchange rate on the day of payment when paid through our contracting and payment system.
- o Where a fee for service payment was agreed in Euros and paid via our internal Finance system in GBP with a HP/ORDM, the amount is then converted into GBP (using the exchange rate) at the time of contracting.
- o Where a fee for service payment was agreed in Euros and paid via our internal Finance system 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

o 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

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

8. Payments to healthcare organisations

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

9. Payments to HPs/ORDMs

- o 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.
- o The names of the HPs/ORDMs are disclosed unless disclosure on a named basis has been objected to and Chiesi has accepted the objection. In such cases, Chiesi has declared the total spend as an aggregate figure as a separate line entry within the required disclosure section.
- o Where a HP has indicated they are independent of any organization, their principle practice has been disclosed as "N/A"
- o 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.
- o Where support has been provided to a HP e.g. travel and accommodation for an event, this is disclosed in the year of the event. This may differ from the year in which the booking was made.

10. Name matching (from multiple sources)

- o 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.
- o 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.

11. Collaborative Working

o Chiesi has not undertaken any Collaborative Working including Joint Working activity during 2022.

12. 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.