

**DISCLOSURE OF TRANSFERS OF VALUE TO
HEALTHCARE PROFESSIONALS AND
HEALTHCARE ORGANISATIONS IN THE UK**

METHODOLOGICAL NOTES

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DISCLOSURE OF 2019 DATA DURING THE COVID 19 PANDEMIC IN 2020

As part of the pharmaceutical industry's annual disclosure of transfers of value to Healthcare Professionals (HCPs), Other Relevant Decision Makers (ORDMs) and Healthcare Organisations (HCOs) via the Disclosure UK platform and in order to ensure accuracy of the published data, the Association of the British Pharmaceutical Industry (ABPI) have written to all of the HCPs, ORDMs and HCOs named in companies' disclosure data ahead of its publication on Disclosure UK at the end of June. Given the unprecedented pressure on the National Health Service (NHS) and HCPs in responding to the COVID 19 pandemic, in April 2020 the ABPI and Prescription Medicines Code of Practice Authority (PMCPA) agreed that it would not be appropriate for industry to write to HCPs, ORDMs or HCOs to request that disclosure data be reviewed. Doing so would add additional work for NHS professionals at this time. To avoid this, and in line with guidance provided by the ABPI, Pharma Mar's 2019 transfer of value data was published June 30th on Disclosure UK in aggregate.

However, the pharmaceutical industry is committed to preserving the integrity of Disclosure UK and transparency in our interactions with HCPs, ORDMs and HCOs. Therefore, in summer the ABPI informed companies that we could re-submit in July the full disaggregated 2019 data to Disclosure UK in line with data and privacy requirements from previous years.

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INTRODUCTION

Pharma Mar S.A. is a member of the European Bio-pharmaceutical Enterprises (EBE), a specialized group of research-based pharmaceutical companies within EFPIA (European Federation of Pharmaceutical Industries and Associations). As such, Pharma Mar S.A. is bound by the EFPIA Code 2019 ^[1] to disclose any amount attributable to Transfers of Value to Healthcare Professionals and Healthcare Organizations in each Reporting Period.

Pharma Mar does not currently have company presence in the United Kingdom and does not promote its products in the United Kingdom. In this regard, Pharma Mar has engaged a third party (a pharmaceutical company) as a commercial and promotional distributor through an exclusive commercialization and distribution agreement, by way of which such distributor has contractually assumed the marketing and promotion of Pharma Mar's authorized product/s in the UK, including the discharge of obligations relating to the documentation and disclosure of Transfers of Value made to Healthcare Professionals, Healthcare Organizations and Patient Organizations, in compliance with all applicable laws, rules and applicable codes of practice in the territory.

The EFPIA Code 2019 ^[1] states in Article 23 (likewise set forth in clause 24.10 of the ABPI Code of Practice 2019 ^[2]) that together with the template describing the Transfers of Value, each Member Company shall publish a note summarizing the methodologies used by it in preparing the disclosures and identifying each category of the Transfers of Value. The note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Transfers of Value for purposes of this Code.

CONTENT

1. General Summary & Country considerations

This methodological note is referred to any Transfer of Value made by Pharma Mar S.A. during 2019 to any HCP practicing their profession in the United Kingdom or HCO headquartered in the United Kingdom. Since disclosures shall be made pursuant to the national code of the country where the Recipient has its primary practice or place of incorporation, as the case may be, Pharma Mar declaration is regulated by the ABPI Code of Practice 2019. ^[2]

During 2019 Pharma Mar S.A. has executed a very limited amount of Transfers of Value to HCPs and HCOs whose primary practice or place of incorporation is respectively in the UK. Transfers of Value made to HCPs/HCOs related to Research & Development in the United Kingdom that can be accurately linked to activities as defined on the Art. 23 of the EFPIA Code 2019 ^[1], would have been declared as an aggregate amount under the “Research and Development Transfers of Value” category. These amounts may include as underlying concepts not only Investigators payments and grants, but also administrative fees, concomitant medication, expenses on diagnostics tools and other similar concepts.

However please note that Pharma Mar has not allocated under the “Research and Development Transfers of Value” category those amounts which Pharma Mar cannot accurately ascertain to have been transferred to the relevant HCP that acts as an investigator in the conduction of a clinical trial, or transferred to a specific HCO, whatever the category of the Transfer of Value may be. In this regard, Pharma Mar shall not include under the “Research and Development Transfers of Value” category for the UK Disclosure any payments done to Clinical Research Organizations (CRO) acting on behalf of Pharma Mar in the conduction of a clinical trial where the amount of the Transfer of Value, the category and/ or final recipient of the Transfer of Value cannot be ascertained in a reliable form under the methodology used by Pharma Mar (e.g. some international trials) and we will disclose those amounts in full in the

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“Research and Development Transfers of Value” section of Disclosure of Pharma Mar in Spain (i.e. the contracting company) instead.

2. Definitions & Abbreviations

EFPIA:	European Federation of Pharmaceutical Industries and Associations
EBE:	European Bio-pharmaceutical Enterprises
Event:	Any promotional meeting, scientific-professional meeting, congress, conference, symposium, in-person or distance educational courses, or any other type of similar activity (including but not limited to expert meetings, visits to manufacturing and research facilities, as well as training meetings for investigators conducting clinical trials and post-authorization studies) organised or sponsored by a pharmaceutical company or under its control.
CRO:	Clinical Research Organizations
GBP:	GBP: Pound sterling
HCO:	Healthcare Organization (for a complete definition of the term you may refer to the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations, Schedule 1 Definition of terms)
HCP:	Healthcare Professional (for a complete definition of the term you may refer to the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations, Schedule 1 Definition of terms)
HCP Code:	EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals, adopted by the EFPIA Board.
Recipient	In accordance with EFPIA HCP/HCO Disclosure Code it is any Health Care Professional or Healthcare Organization as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Europe
Transfers of Value	Under the EFPIA HCP/HCO Disclosure Code are defined as direct and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only Medicinal Products exclusively for human use. Direct transfers of value are those made directly by a Member Company for the benefit of a Recipient. Indirect transfers of value are those made on behalf of a Member Company for the benefit of a Recipient, or transfers of value made through an intermediate and where the Member Company knows or can identify the HCP/HCO that will benefit from the Transfer of Value.
UK:	United Kingdom of Great Britain

3. Methodology used

Transfers of Value which may comprehend donations, grants and benefits in kind; sponsorship of attendance of Healthcare Professionals at meetings; fees paid to Healthcare Professionals; contributions to the cost of meetings (including registration fees, accommodation and travel) shall be usually preceded and supported by a letter sent by the HCP, requesting the aforementioned contribution. This letter is usually stored by the department responsible at that time for the activity. Transfers of Value for a certain event can be committed up to a total amount previously approved by the Pharma Mar Management. Any contribution to HCOs or HCPs has to be requested on written form; every request must be evaluated and approved on a case by case basis by the Pharma Mar Management. Records with the details (name, working address, amounts transferred) of the HCP or HCO to whom any Transfer of Value was done are kept on electronic format. For those Events, where the approval is based on a budgeted quantity, reconciliation is done once the invoices arrive, aiming to reflect the real amount spent and not the budgeted amount.

Throughout 2019, Pharma Mar has required every HCP/HCO to whom it has made a Transfer of Value to provide identification and grant personal consent in a formal written agreement thereby authorizing Pharma Mar to obtain and store the relevant personal data according to Spanish Data Protection Laws, and to appropriately disclose and publish the Transfers of Value made to such HCPs/HCOs on an individual basis.

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Other issues and criteria applied

To the best of Pharma Mar's knowledge, the following criteria have been used to compile and summarize the information.

- Amounts are disclosed in GBP, and do not include VAT. Where required the amount in Euros would have been translated into GBP multiplying by a factor of 0.8543, which is the average of all daily exchange rates of the Euro against GBP in 2019 ^[4].
- All the amounts disclosed correspond to Transfers of Value that took place exclusively during 2019
- Where costs cannot be individually identified but can be applied to a number of individuals, the total cost has being split proportionally among them i.e. An invoice from a hotel, for an accommodation total, would have been divided into "nights" and applied proportionally to the HCP hosted.
- If a HCP cancels his/her attendance to a meeting/congress, the expense already incurred by Pharma Mar will be not allocated to him/her - as long as feasible (e.g. very late notifications).
- If a HCP owns a limited liability company, Pharma Mar will disclose the amounts under the HCP's name.

References

1. European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice 2019
2. ABPI Code of Practice for the Pharmaceutical Industry, 2019.
3. Pharma Mar S.A., "Pharma Mar Web" [Online]. Available: <https://www.pharmamar.com/>.
4. HM Revenue & Customs. [Online]. Available: <https://www.gov.uk/government/publications/exchange-rates-for-customs-and-vat-yearly> [Accessed 21 February 2020]