

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

**METHODOLOGICAL NOTES**

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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 on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations<sup>[1]</sup>, to disclose any amount attributable to Transfers of Value<sup>1</sup> to Healthcare Professionals and Healthcare Organizations in each Reporting Period. Pharma Mar Ltd. is a fully owned subsidiary of Pharma Mar S.A. in the United Kingdom, and as such is responsible of any commercial/promotional activity in the country. Pharma Mar Ltd. is a member of the Association of the British Pharmaceutical Industry (ABPI), and therefore bound by its Code of Practice of the Pharmaceutical Industry. EFPIA Code of Disclosure Transfers of Value<sup>[1]</sup> states on Section 3.05. (likewise set forth in clause 24.10 of the ABPI Code of Practice 2016<sup>[2]</sup>) 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.

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<sup>1</sup> 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.*

## CONTENT

### 1. General Summary & Country considerations

This methodological note is referred to any Transfer of Value made during 2016 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<sup>2</sup> has its primary practice or place of incorporation, as the case may be, Pharma Mar declaration is regulated by the ABPI Code of Practice 2016<sup>[2]</sup>

Most of the Transfers of Value made during 2016 to HCOs and HCPs to Recipients, whose primary practice, or place of incorporation is respectively in UK, have been directly executed by Pharma Mar Ltd., since its incorporation on July 1<sup>st</sup> 2015. Nevertheless Pharma Mar S.A. as the mother company of Pharma Mar Ltd. has executed either directly or on behalf of Pharma Mar Ltd., a limited amount of Transfers of Value to HCOs and HCPs whose primary practice, or place of incorporation is respectively in the UK. Specifically in the case of Transfers of Value falling into the "Research and Development Transfers of Value" category, all the expenditure was done by Pharma Mar S.A., as it comprehended the expenses of Educational Events carried out by the Medical Department. For the sake of clarity and in order to ease the supervision and verification of Pharma Mar's impact on the HCPs/HCOs in the UK during 2016, Pharma Mar has decided that any Transfer of Value made to HCOs or HCPs whose primary practice, or place of incorporation is respectively in UK, shall be disclosed under Pharma Mar Ltd., irrespective of what legal entity did it. Transfers of Value made to HCPs/HCOs related to Research & Development that can be clearly linked to activities as defined on the Art 3.04 & Schedule 1 of the EFPIA Code on Disclosure of Transfers of Value<sup>[1]</sup>, have been declared as an aggregate amount under the "Research and Development Transfers of Value" category. The amounts disclosed under "Research & Development" caption correspond to payments made to HCOs and may include as underlying

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<sup>2</sup> In accordance with EFPIA HCP/HCO Disclosure Code, "Recipient" 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

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 this amount shall not include those cases in which Pharma Mar cannot ascertain the specific amount which has been transferred to the relevant HCP that acts as an investigator in the conduction of a clinical trial, or which has been transferred to a 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 any payments done to Clinical Research Organizations 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.

## 2. 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 Local entity responsible at that time for the Promotional Activities in the UK. Transfers of Value for a certain event can be committed up to a total amount previously approved by the Pharma Mar Ltd. Management. Any contribution to HCOs or HCPs has to be requested on written form; every request is evaluated and approved on a case by case basis by the Pharma Mar Ltd. 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.

In general Pharma Mar Ltd., requires every HCP/HCO to whom it makes a Transfer of Value to register on its online application database designated “Pharma Mar Disclosure Code”<sup>[4]</sup>, in order to

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identify themselves and to grant their consent to authorize Pharma Mar to obtain and store their personal data according to Spanish Data Protection Laws, and finally to grant or refuse their consent to Pharma Mar to disclose and publish the Transfers of Value made in their favor on an individual basis. The “Pharma Mar Disclosure Code” is a secured database, in which the identity of the registered users is verified by means of a two-steps verification process using both their e-mail address and via SMS to user’s mobile phone. All the HCPs/HCOs have access to their recorded personal data at any time and by way of a specific password they may amend or change their personal information and authorizations at any time. In addition the Data Base is manually linked to Pharma Mar’s proprietary CRM database for a better identification of each registered individual.

To issue the current Disclosure of Payments to HCP/HCO in UK during 2016, all the electronic records of Transfers of Value have been compiled and reviewed to avoid HCP/HCO duplications. The final list of HCPs/HCOs has been manually confronted with the obtained from the “Pharma Mar Disclosure Code” database in order to identify those individuals who request an aggregated declaration of the Transfers of Value made in their favor. On certain occasions in which the engagement with the HCP/HCO is not possible through the foresaid “Pharma Mar Disclosure Code” database, the engagement with the HCP/HCO shall be arranged by way of a formal written agreement which shall identify the Recipient of the Transfer of Value, the subject matter of the arrangement, the amount of the Transfer of Value as well as other material provisions that may be deemed necessary between the parties. In case the Recipient of the foresaid Transfer of Value is a HCP, a specific provision in the agreement addresses Recipient’s right to grant his/her consent to Pharma Mar in order to authorize the disclosure and publication of the relevant Transfer of Value.

The immediate implementation, in May 25th 2018, of the new Regulation (EU) 2016/679, and consequently the obligation to comply with a new and more stringent consent of disclosure requires Pharma Mar, in order to fulfil all the legal requirements on time, that the 2016 data report would be resubmitted in an aggregated format.



### 3. 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 has been translated into GBP multiplying by a factor of 0,8237, which is the average of all daily exchange rates of the Euro against GBP in 2016.
- All the amounts disclosed correspond to Transfers of Value that took place exclusively during 2016
- 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, has been divided into "nights" and applied proportionally to the HCP hosted.
- When despite Pharma Mar's efforts, the HCP/HCO neither gave its permission, nor its refusal to the individual publication of their Transfers of Value; Pharma Mar S.A. has disclosed the amounts transferred on an aggregated basis.

## ABBREVIATIONS

**EFPIA:** European Federation of Pharmaceutical Industries and Associations

**EBE:** European Bio-pharmaceutical Enterprises (EBE)

**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.

**UK:** United Kingdom of Great Britain

## REFERENCES

- [1] EFPIA European Federation of Pharmaceutical Industries and Associations, "Responsible Transparency," 2016. [Online]. Available: <http://transparency.efpia.eu/>. [Accessed 29 02 2016].
- [2] ABPI, "ABPI Code of Practice for the Pharmaceutical Industry," 2016. [Online]. Available: [http://www.abpi.org.uk/our-work/library/guidelines/Documents/code\\_of\\_practice\\_2016.pdf](http://www.abpi.org.uk/our-work/library/guidelines/Documents/code_of_practice_2016.pdf). [Accessed 29 February 2016].
- [3] Pharma Mar S.A., "Pharma Mar Web," [Online]. Available: <https://www.pharmamar.com/>.
- [4] Pharma Mar S.A., "Pharma Mar Disclosure Code," Softpoint , 2015. [Online]. Available: <https://www.pharmamar-disclosurecode.com/en/>.