

DISCLOSURE OF TRANSFERS OF VALUE TO ITALIAN HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

METHODOLOGICAL NOTES

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METHODOLOGICAL NOTES ACCOMPANYING, DATA DISCLOSURE OF TRANSFERS OF VALUE TO ITALIAN HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

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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 2020 [1] to disclose any amount attributable to Transfers of Value to Healthcare Professionals and Healthcare Organizations in each Reporting Period.

The EFPIA Code 2020 ^[1] states in Article 23 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 in 2020 to any HCP practicing their profession in Italy or HCO headquartered in Italy. Since disclosures shall be made pursuant to the national code of the country where the Recipient¹ has its physical address, Pharma Mar declaration is regulated by the Codice Deontologico from Farmindustria [2]

Transfers of Value to Italian HCP/HCO related to Research & Development that can be clearly linked to activities as defined on the Art 23 of the EFPIA Code 2020 [1], could 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 S.r.L. 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 S.r.L. shall not include under the “Research and Development Transfers of Value” category for the Italian 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 PharmaMar

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(e.g. some international trials) and we will disclose those amounts in full in the “Research and Development Transfers of Value” section of Disclosure of Pharma Mar S.A. in Spain (i.e. the contracting company) instead.

According to new version of EFPIA Code any Transfer of Value made providing financial support and/or significant indirect or non-financial support to a Patient Organization or with whom Pharma Mar has engaged to provide contracted services by a Patient Organization will be disclosed in this report separately. List of Patient Organizations includes a description of the nature of the support or services provided without the divulging confidential information. Additionally it will be included the monetary value of financial support and of invoiced costs, the non-monetary benefit that the PO receives when the non-financial support cannot be assigned to a meaningful monetary value and/or the total amount paid per Patient Organization over the Reporting Period.

2. Covid-19 Disclaimer

Pharma Mar has made its best human and technical effort to properly disclose all Transfers of value provided during 2020 period but even though and due to the challenging and exceptional times lived because of global pandemic and all derived cancellations and activities postponed, we are aware that minor accidental errors may had occurred. Pharma Mar is strongly committed with transparency and accuracy and therefore if despite our best efforts, we were not able to properly reflect all Transfers of Value or a ToV that finally did not occurred was included by error, we will review it and analyze and provide accordingly a complete and adequate response and/or correct information as soon as possible.

3. Methodology used

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 2020, 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 Italian Data Protection Laws, and to appropriately disclose and publish the Transfers of Value made to such HCPs/HCOs on an individual basis.

Pharma Mar contacts the HCP/HCO via email to obtain the necessary consent to disclose and publish the Transfers of Value made to the Recipient on an individual basis. If individual consent is not obtained, the information is then disclosed in aggregated manner.

4. Other issues and criteria applied

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

- Amounts are disclosed in Euros, and do not include VAT.
- All the amounts disclosed correspond to Transfers of Value that took place exclusively during 2020.
- 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, could 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.

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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
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.

REFERENCES

1. European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice 2019
2. Codice deontologico Farmindustria Novembre 2020.

Pharma Mar S.A., "Pharma Mar Web" [Online]. Available: <https://www.pharmamar.com/>.

LEGAL NOTICE

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If needed, please contact the country at: info@pharmamar.it