

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

METHODOLOGICAL NOTES

Date of Issue: June, 2019
Country Scope: Italy
Version: 1.0

CONTENTS

INTRODUCTION.....3

CONTENT.....3

1. General Summary & Country considerations.....3

2. Methodology used.....4

3. Other issues and criteria applied.....5

ABBREVIATIONS6

REFERENCES.....6

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

EFPIA Code of Disclosure Transfers of Value ^[1] states on Section 3.05. 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 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 the Code.

CONTENT

1. General Summary & Country considerations

This methodological note is referred to any Transfer of Value made in 2018 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]

¹ 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

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

Transfers of Value to Italian HCP/HCO 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 [1], have been declared as an aggregate amount under the “Research and Development Transfers of Value” category.

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 [1], have been declared as an aggregate amount under the “Research and Development Transfers of Value” category. The amounts disclosed under "Research & Development" caption corresponds to payments made to HCOs and 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 the foresaid 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 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 is 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 made 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., requires every HCP/HCO to whom it makes a Transfer of Value to grant their consent to authorize Pharma Mar to obtain and store their personal data according to Spanish Data Protection Laws, and 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. 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.

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.

3. 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 2018
- 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.

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

- 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)

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.

REFERENCES

[1] EFPIA European Federation of Pharmaceutical Industries and Associations, "Responsible Transparency," 2016. [Online]. Available: <http://transparency.efpia.eu/> [Accessed 25 July 2018]

[2] Farindustria , "Codice Deontologico," 18 gennaio 2019.