

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

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 [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 Transfers of Value made in 2016 to any HCP practicing their profession in The Netherlands or HCO headquartered in The Netherlands. Since disclosures shall be made pursuant to the national code of the country where the Recipient^a has its physical address, Pharma Mar declaration is regulated by the Code of Conduct for Pharmaceutical Advertising from the Foundation for the Code for Pharmaceutical Advertising [2]

^a 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

It is worth noting that Pharma Mar S.A. did not have any subsidiary in The Netherlands in 2016. Accordingly, all the promotional activities conducted in The Netherlands during 2016 were executed, by a dedicated Sales Team of Novex Pharma Laboratorio, S.L working on behalf of Pharma Mar, S.A. In this regard during 2016 Transfers of Value have been made indistinctly by Pharma Mar S.A or by Novex Pharma Laboratorio, S.L on behalf of Pharma Mar S.A. Therefore for the sake of providing more transparency, and clarity on the disclosure of Transfers of Value made during 2016 any Transfers of Value either made directly by, or on behalf of Pharma Mar S.A, are disclosed under Pharma Mar S.A's. name.

Transfers of Value to Dutch 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. 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

Any contribution to HCO or HCP has to be requested on written form; every request is evaluated and approved on a case by case basis by the Pharma Mar Sales 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.

The engagement with the HCP/HCO was 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 Recipients' right to grant his/her consent to Pharma Mar in order to authorize the disclosure and publication of the relevant Transfer of Value. To issue the current Disclosure of Payments to HCP/HCO in The Netherlands during 2015, all the electronic records of transfers of value have been compiled and reviewed to avoid HCP/HCO duplications. The final list of HCP/HCO has been manually confronted with this obtained from the written agreements in order to identify those individuals/organizations which do request an aggregated declaration of their Transfers of Value.

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 Euros, and do not include VAT.
- 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)

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. [En línea]. Available: <http://transparency.efpia.eu/>. [Último acceso: 01 June 2017].
- [2] Foundation for the Code for Pharmaceutical Advertising , «Code of Conduct for Pharmaceutical Advertising,» 2015. [En línea]. Available: <http://www.cgr.nl/en-GB/Gedragcode-Genesmiddelenreclame>. [Último acceso: 01 June 2017].