

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

## METHODOLOGICAL NOTES

Date of Issue:	June 2017
Country Scope:	Sweden, Poland, Norway & Denmark
Version:	2.0



## CONTENTS

INTRODUCTION .....	5
CONTENT .....	5
1. General Summary & Country considerations.....	5
2. Other issues and criteria applied.....	7
ABBREVIATIONS.....	7
REFERENCES .....	8



## 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 2016 in Sweden, Poland, Norway and Denmark.

Pharma Mar S.A. did not have subsidiaries in Sweden, Poland, Norway or Denmark during 2016, thus all the commercial activities conducted with Pharma Mar's products in those countries were carried out by our partner Swedish Orphan Biovitrum AB (SOBI) by virtue of the commercialization and distribution agreement entered into effective as of August 2<sup>nd</sup> 2007, and its further

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

amendments. SOBI conducts all the marketing and promotional activities related to Yondelis<sup>®</sup>, according to EFPIA Code of Practice or to the applicable Local Code of Ethics, and therefore shall perform the obligations of documentation and disclosure of the relevant Transfers of Value to Healthcare Professionals and Healthcare Organizations in their territory of operations for the calendar year 2016.

Notwithstanding the above, Pharma Mar S.A, declares on its own behalf:

- A. Transfers of Value 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]. 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 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.

- B. Transfers of Value to HCO/HCP done in the context of International Educational Activities, directly organized and handled by Pharma Mar S.A through its International Medical Department.

## 2. 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

## 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," 6 June 2014. [Online]. Available: [https://www.efpia.eu/media/24302/3a\\_efpia-hcp-code-2014.pdf](https://www.efpia.eu/media/24302/3a_efpia-hcp-code-2014.pdf). [Accessed 20 June 2017].

