

DISCLOSURE OF TRANSFERS OF VALUE TO PATIENT 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 2019 EFPIA Code of Practice^[1] and its requirements regarding Disclosure of any amount attributable of Transfers of Value from Pharmaceutical Companies to Patient Organizations (POs).

Patients benefit must be at the heart of stakeholders and decision makers. POs can partner with different stakeholders in the healthcare ecosystem, including pharmaceutical companies, to help this ecosystem to be better and more holistically focused on patients. The correct and proper engagement can have a positively impact on healthcare and life cycle of a medicine^[2]. This is because POs can make use of the patient's expertise and experiences to improve the level of care the patients receive. Companies are looking at new ways to incorporate patient insights and developing better collaboration with patients^[3] and POs in a transparent and ethical way. POs can gather information on diseases and treatments and raise public awareness, inform companies in their development of new medicines, gather information on the availability of clinical trials for patients, contribute into discussion of government committees, provide funding into research, or contribute into the development of patient support programs, just to mention a few.

The EFPIA Code (for short) states in Article 24 that together with the disclosure of the Transfers of Value, each Member Company shall publish a note summarizing the methodologies used by them 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 can 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.

METHODOLOGICAL NOTES ACCOMPANYING, DATA DISCLOSURE OF TRANSFERS OF VALUE TO PATIENT ORGANISATIONS

CONTENT

1. General Summary & considerations

This methodological note is referred to any Transfer of Value made during 2019 to any PO.

Most of the Transfers of Value made during 2019 to POs have been directly executed by Pharma Mar S.A. Nevertheless Pharma Mar S.A. as the mother company of the other affiliates based in Europe (i.e. in France, Belgium, Germany, Italy and Austria) may execute either directly or on behalf of its affiliates , Transfers of Value to POs and will also disclose these.

2. Definitions & Abbreviations

EFPIA:	European Federation of Pharmaceutical Industries and Associations
EFPIA Code:	EFPIA Code of Practice
Caregiver:	Any person supporting individual patients. They can be family members or friends, as well as paid or volunteer helpers.
Donation:	A financial or non-financial contribution freely given to an organization (normally a registered charity) for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services for the benefit of the donor in return.
EBE:	European Bio-pharmaceutical Enterprises
EUPATI:	European Patients Academy on Therapeutic Innovation
Grant:	This term is used in many countries instead and indistinctly of “donation”. It's normally linked also to an specific and timebound activity (e.g. typically an educational grant).
Patient:	Any persons with personal experience of living with a disease and that may receive treatment with a medical product or technology. They may or may not have technical or regulatory knowledge but they can contribute with their subjective disease and treatment experience.
Patient Expert:	Any person that, in addition to disease-specific expertise, have the technical knowledge in medicinal product Research & Development and/or regulatory affairs through training (e.g. EUPATI Fellows or similar) or experience.
Patient Organisation:	They are independent not-for-profit organisations (including umbrella organisations to which they belong), normally composed of patients and/or caregivers. They provide support to people affected by an illness and advocate patients' rights, develop and support disease awareness campaigns and patient information in their therapeutic area.
Sponsorship:	A financial or non-financial contribution given to a third party by or on behalf of a Company for a specific purpose, permitted by law and which requires a compensation. They are considered promotional in nature. It includes contributions

	to support an activity or event attended, performed, organised or created by a Healthcare Organisation, a Patient Organization or other third party.
Transfers of Value:	Under the EFPIA Code these 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 or 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 Individual Organisation or Person that will benefit from the Transfer of Value.

METHODOLOGICAL NOTES ACCOMPANYING, DATA DISCLOSURE OF TRANSFERS OF VALUE TO PATIENT ORGANISATIONS

3. Methodology used

Transfers of Value which may comprehend donations, grants and benefits in kind; sponsorship; fees paid to POs; contributions to the cost of meetings (including registration fees, accommodation and travel) shall be usually preceded and supported by a letter sent by the POs requesting the aforementioned contribution.

This letter submitted by the POs is usually stored by Pharma Mar headquarters (i.e. Pharma Mar, S.A.) or the Local entity (i.e. each affiliate) responsible at that time for making the Transfer of Value. 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 POs has to be requested on written form; and every request evaluated and approved on a case by case basis by the Pharma Mar Management. Records with the details (e.g. written agreement) of the PO to whom any Transfer of Value was made to 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 date of period for Disclosure, is normally based on the date of the payment (e.g. for Direct Transfer of Value or multi-year contracts) but if more appropriate, it can be also based on the date of event (e.g. benefit in kind/non-financial support towards an event).

In any case, and to the extent required by the applicable law or country code of practice Pharma Mar shall require every PO to whom it made a Transfer of Value to provide its consent to Pharma Mar, in order to disclose and publish the Transfers of Value made in its favor on an individual basis. All Engagements with a PO are arranged by way of a formal written agreement.

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 local currency or Euros, and do not include VAT.
- All the amounts disclosed correspond to Transfers of Value that took place exclusively during 2019

References:

1. European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice 2019.
2. EFPIA Working together with Patients (June 2019)
3. EFPIA Working together with Patient Groups (September 2017)