

Mitsubishi Tanabe Pharma Group Methodology

Transfers of Value to Patient Organisations (POs) in Europe

1. Introduction

- 1.1 Under the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice 2019 pharmaceutical companies are required to document and disclose Transfers of Value made to POs in Europe on an annual basis.
- 1.2 This guidance is applicable to and documents the process to be followed for the disclosure of Contracted Services, including Sponsorships, Donations & Grants made by MTPG Companies to POs in Europe.
- 1.3 It is the responsibility of the relevant MTPG staff to determine that the proposed Transfer of Value to a PO is permitted under the relevant applicable law and in accordance with relevant SOPs.
- 1.4 The primary contacts regarding this guidance and enforcement of this process are Dr Martin Davies, MTPE Managing Director and Ms Ashley McGurl, Assistant Manager, Corporate Management Department.

2. Definitions

- 2.1 **Affiliate:** Any MTPG Company which is directly or indirectly controlled by, or is under common control with, such MTPG Company where Control means the beneficial ownership of more than fifty per cent (50%) of the issued share capital or the legal power to direct or cause the direction of the general management of the MTPG Company.
- 2.2 **EFPIA Code:** The European Federation of Pharmaceutical Industries and Associations EFPIA Code of Practice 2019 – Chapter 5, Article 24.
ABPI Code: The Association of the British Pharmaceutical Industry Code of Practice 2021 – Clause 29.
AKG Code: Code of Conduct of the members of The Medicinal Products and Cooperation in Health Sector, (*Arzneimittel und Kooperation im Gesundheitswesen e.V – AKG*) 2015 – Patient Code
Pharma Corporation Code: Code of Conduct of the Pharmaceutical Industry in Switzerland 2020
- 2.3 **Europe:** in terms of Disclosure Europe refers to those countries for which there is an EFPIA Member Association:

Austria	Belgium	Bulgaria	Croatia
Cyprus	Czech Republic	Denmark	Estonia
Finland	France	Germany	Greece
Hungary	Ireland	Italy	Latvia
Lithuania	Malta	The Netherlands	Norway
Poland	Portugal	Romania	Russia
Serbia	Slovakia	Slovenia	Spain

Sweden
United Kingdom

Switzerland

Turkey

Ukraine

2.4 **Patient Organisation (PO):** a non-for-profit legal entity or organisation mainly comprising of patients and/or caregivers or relative organisation that represents and/or supports the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is within Europe.

2.5 **Event:** All promotional, scientific or professional meetings, congresses, conferences, symposia and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) which are organised by, sponsored by or on behalf of an MTPG Company.

2.6 **Donations & Grants:** collectively mean providing funds, benefits-in-kind or services freely given for the purpose of supporting healthcare, scientific research, or education, with no consequent obligation on the recipient organisation, institution, and the like to provide goods or services in the benefit of the pharmaceutical company in return.

2.7 **MTPC** means Mitsubishi Tanabe Pharma Corporation and its Affiliates – including NeuroDerm and Medicago.

2.8 **MTHA** means Mitsubishi Tanabe Holdings America, Inc. and its Affiliates.

2.9 **MTPE** means Mitsubishi Tanabe Pharma Europe Ltd and its Affiliates.

2.10 **MTPD** means Mitsubishi Tanabe Pharma GmbH and its Affiliates.

2.11 **MTPG Company** means MTPC, MTHA, MTPE and MTPD.

2.12 **Transfer of Value (ToV)** means a direct or indirect Transfer of Value, whether in cash, in kind or otherwise which is made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only Medicinal Products exclusively for human use:

(a) **direct** transfers of value are those made directly by a MTPG Company for the direct benefit of the PO;

(b) **indirect** transfers of value are those made by a third party on behalf of a MTPG Company for the benefit of the PO, or financial /non-financial support made through a third party and where the MTPG Company can identify the PO that will benefit from it;

3. **Types of Transfers of Value**

3.1 The following types of ToV's are captured under this process:

3.1.1 **Patient Organisations (POs):**

A)	Donations and Grants	<p>In General Donations are physical items, services or benefits-in-kind which may be offered or requested, Grants are the provision of funds and may only be made if:</p> <ul style="list-style-type: none"> • they are made for the purpose of supporting healthcare or research. • they are documented and kept on record by the donor/grantor; and • they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. • this may include Medical & Educational Goods & Services (MEGS) • requires Certification of the interaction in advance (UK). <p>Donations and Grants to individuals is strictly prohibited.</p>
B)	Contribution to costs related to Events	<p>Contributions of costs made to POs, or individuals representing a PO, including sponsorship to attend Events, such as:</p> <ul style="list-style-type: none"> • Registration fees. • Sponsorship agreements with POs or with third parties appointed by a PO to manage an Event, • Travel and accommodation fees to support the attendance of individuals to an event. • When providing sponsorship of events/meetings to an organisation, such contributions may include costs for subsistence (food & drink)
C)	Contracted Services	<p>Transfers of Value resulting from or related to agreements between MTPG Company and institutions, organisations or associations of PO's under which such institutions, organisations or associations provide any type of services to MTPG Company or any other type of funding that is not covered by disclosure as either a Donation/Grant or Contribution to costs related to Events.</p>

4. **Process for collating Transfers of Value**

4.1 Each MTPG Company must collate any support provided using the **Transfer of value - PO Form**. For indirect services, the Form should either be completed internally or sent to the third party involved for completion and return.

4.2 Each MTPG Company is responsible for the collation of support provided in a calendar year period (1st January – 31st December):

4.2.1 direct ToV that it makes in its own name to POs;

4.2.2 direct ToV to POs that it manages for and on behalf of another MTPG Company;

4.2.3 indirect ToV provided by third parties on its own behalf or on behalf of another MTPG Company where it is managing for and on behalf of that MTPG Company;

4.2.4 Each ToV with a PO should be listed individually on the form, even if there are multiple ToV's to the same PO during the period.

4.3 Responsibilities

4.3.1 Direct Transfers of Value:

(i) Each **Head of Department** who authorises a non-research related ToV where a MTPG Company contracts a PO directly, must ensure that the **Transfers of Value – PO Form** is completed.

(ii) Each **Project Manager** is responsible for collating research related ToV's in relation to their own projects.

4.3.2 Indirect Transfers of Value

(i) Each **Project Manager** managing relevant third party relationships has overall responsibility for ensuring completion and return of the **Transfer of Value - PO Form** by that third party.

4.3.3 Completed Forms must be submitted to **MTPE's Finance Department** by the set February deadline instructed by Finance Department.

5. **Disclosure**

5.1 Transfers of Value are publicly disclosed on behalf of MTPG Companies in accordance with applicable disclosure and transparency requirements in accordance with Appendix 1 as follows:

5.1.1 where made to POs: in accordance with the disclosure requirements of the association where the registered place of business is located.

5.1.2 Data tables by Country will only be published if a ToV has taken place during the period.

- 5.2 Each PO disclosure will contain a clear description of the Transfer of Value that will enable the reader to understand the nature of the support or the agreements.
 - 5.2.1 The monetary value for each financial contribution (grant or sponsorship)
 - 5.2.2 The monetary value for each non-financial and /or indirect support (donation)
 - 5.2.3 If the non-financial and or/indirect support cannot be assigned a monetary value, the published information must describe clearly the non-monetary value that the PO receives.
- 5.3 Where MTPG members have engaged with a PO on multiple occasions throughout the period, a total monetary value will be published for the period with further detail of each ToV, including details of each financial and non-financial support provided.
- 5.4 Disclosure will be made via the MTPE website which is publicly accessible (<http://www.mt-pharma-eu.com/transparency/>) and according to the requirements of the relevant association in the case of European countries where there is a member MTPG company established no later than 30th June of each calendar year.
- 5.5 Transfers of Value are disclosed in accordance with this policy will remain publicly accessible in accordance with country requirements for a period of three (3) years following disclosure.
- 5.6 MTPE Corporate Management will archive PO disclosures made for a period of at least five (5) years (or otherwise in accordance with applicable data protection laws).

Appendix 1

MTPG Methods of Disclosure on a Country by Country Basis

Country	MTPG Company Responsible for Disclosure	Language	Location of Disclosure
*Austria	MTPE	English / German	MTPE Website in accordance with AKG Transparency Rule, AKG Code of Conduct – Patient Code 2015
Belgium	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Bulgaria	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Croatia	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Cyprus	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Czech Republic	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Denmark	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Estonia	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
France	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Finland	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
*Germany	MTPE	English / German	MTPE Website in accordance with AKG Transparency Rule, AKG Code of Conduct – Patient Code 2015
Greece	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Hungary	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Ireland	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Italy	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Latvia	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Lithuania	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Malta	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Netherlands	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Norway	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Poland	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Portugal	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Romania	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019

Serbia	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Slovakia	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Slovenia	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Spain	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Sweden	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
*Switzerland	MTPE	English / German / French	MTPE Website in accordance with vips (Association of Pharmaceutical Companies in Switzerland) Pharma Corporation Code May 2020
Turkey	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
Ukraine	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5, Article 24 2019
*United Kingdom	MTPE	English	MTPE Website in accordance with ABPI Code of Practice, Clause 29 2021, the Disclosure UK platform will publish this link if any interactions took place within the UK.

*Locations of established MTPG companies