

Mitsubishi Tanabe Pharma Group Methodology

Transfers of Value to Healthcare Professionals (HCP) and Healthcare Organisations (HCO) 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 HCOs and HCPs in Europe on an annual basis.
- 1.2 This guidance is applicable to and documents the process to be followed for the disclosure of Transfers of Value made by MTPG Companies to HCOs and HCPs in Europe.
- 1.3 It is the responsibility of the relevant MTPG staff to determine that the proposed Transfer of Value to a HCP or HCO 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.
ABPI Code: The Association of the British Pharmaceutical Industry Code of Practice 2021 – Clause 28.
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 – Section 6.
Pharma Corporation Code: Code of Conduct of the Pharmaceutical Industry in Switzerland 2020 – Section 2
- 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 **Healthcare Organisation (HCO):** Any legal person:
- (a) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organizational form) such as hospital, clinic, foundation, university, or other teaching institution or learned society whose business address, place of incorporation or primary place of business is in Europe; **or**
 - (b) through which one or more HCPs provide services.
- 2.5 **Healthcare Professional (HCP):** Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of their professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe.
- 2.6 **Other Relevant Decision Maker:** refers to someone with a role that could directly influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who is not a healthcare professional
- 2.7 **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.
- 2.8 **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.
- 2.9 **Collaborative Working:** refers to pharmaceutical companies working with other organisations to deliver initiatives which either enhance patient care or are for the benefit of the patients or alternatively benefit the healthcare system and, as a minimum, maintain patient care.
- 2.10 **MTPC** means Mitsubishi Tanabe Pharma Corporation and its Affiliates – including NeuroDerm and Medicago.
- 2.11 **MTHA** means Mitsubishi Tanabe Holdings America, Inc. and its Affiliates.
- 2.12 **MTPE** means Mitsubishi Tanabe Pharma Europe Ltd and its Affiliates.
- 2.13 **MTPD** means Mitsubishi Tanabe Pharma GmbH and its Affiliates.
- 2.14 **MTPG Company** means MTPC, MTHA, MTPE and MTPD.

- 2.15 **Transfer of Value** 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 HCP or HCO;
 - (b) **indirect** transfers of value are those made by a third party on behalf of a MTPG Company for the benefit of the HCO or HCP, or transfers of value made through a third party and where the MTPG Company can identify the HCO/HCP that will benefit from it;
 - (c) **non-research related** transfers of value are those defined in sections 3.1.1 and 3.1.2 which are not related in any way to a MTPG Company's research and development activities and that must be collated and disclosed on an individual HCO/HCP basis; and
 - (d) **research related** transfers of value are those defined in sections 3.1.1 and 3.1.2 that are related to the planning and/or conduct of research and development activities as defined at section 3.1.3.

3. Types of Transfers of Value

3.1 The following types of Transfers of Value are captured under this process:

3.1.1 Healthcare Organisations (HCOs):

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	Contributions made through HCOs or third parties, including sponsorship for HCPs to attend Events, such as:

		<ul style="list-style-type: none"> • Registration fees. • Sponsorship agreements with HCOs or with third parties appointed by a HCO 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	Transfers of Value resulting from or related to agreements between MTPG Company and institutions, organisations or associations of HCPs 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.
D)	Collaborative Working	<p>There should be a significant contribution from each party to the agreement and be the pooling of skills, experience and/or resources from all parties involved</p> <ul style="list-style-type: none"> • requires Certification of the interaction in advance (UK). • A summary of the agreement must be published on corporate website before arrangements are implemented. • Includes Joint Working

3.1.2 Healthcare Professionals (HCPs):

A)	Contribution to costs related to Events	<p>Contributions to HCPs directly or made through HCOs for the benefit of HCPs, related to Events, including:</p> <ul style="list-style-type: none"> • Registration fees; and • Travel and accommodation <p>Where possible disclosures should take place against the individual and not the Organisation.</p>
B)	Contracted Services	Transfers of Value resulting from or related to agreements between MTPG Company and HCPs under which HCPs provide any

		<p>type of services to MTPG Company or any other type of funding that is not covered by Contribution to costs related to Events.</p> <p>This includes any employee of a pharmaceutical company whose primary occupation is that of a practicing health professional</p>
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3.1.3 **Research and Development Transfers of Value:**

Research and Development Transfers of Value include transfers of value to HCPs or HCOs related to the **planning and/or conduct** of:

- (i) non-clinical studies (as defined by OECD Principles on Good Laboratory Practice);
- (ii) clinical trials (as defined by EU Directive 2001/20/EC); or
- (iii) non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of HCPs specifically for the study

3.1.4 In relation to research and development activities, MTPG is the owner of all compounds subject to the developmental activities described in paragraph 3.1.3 above.

3.2 A summary of the main types of Transfers of Value, both research related and non-research related is set out at Appendix 1.

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

4.1 Each MTPG Company must collate transfers of value using the **Direct Transfer of Value Form**. For indirect transfers of value, the **Indirect Transfer of Value 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 Transfers of Value made in a calendar year period (1st January – 31st December):

- 4.2.1 direct transfers of value that it makes in its own name to HCOs and HCPs;
- 4.2.2 direct transfers of value to HCOs and HCPs that it manages for and on behalf of another MTPG Company;
- 4.2.3 indirect transfers of value made 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 non-research related transfers of value must be collated on an individual HCO/HCP basis.

- 4.2.5 research related transfers of value must be collated as an aggregate figure on a country basis.
- 4.3 Responsibilities
- 4.3.1 Direct Transfers of Value:
- (i) Each **Head of Department** who authorises a non-research related Transfer of Value where a MTPG Company contracts a HCO or HCP directly, must ensure that the **Direct Transfers of Value Form** is completed.
 - (ii) Each **Project Manager** is responsible for collating research related transfers of value 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 **Indirect Transfer of Value Form** by that third party.
- 4.3.3 Completed Transfer of Value 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 2 as follows:
- 5.1.1 where made to HCOs: in accordance with the disclosure requirements of the association where their primary place of business is located;
 - 5.1.2 where made to HCPs: in accordance with the disclosure requirements of the association where their principal place of practice is located;
 - 5.1.3 where for research and development purpose: in the aggregate on a country by country basis.
- 5.2 Where a Transfer of Value to an individual HCP is made via their HCO, it will only be disclosed once. Where possible disclosure will be made on an individual basis
- 5.3 Where the agreement under which the Transfer of Value is made does not contain adequate provisions to allow for disclosure or in the event that a HCP withdraws their consent to such disclosure, MTPE will disclose the value of such transfers of value on an aggregate basis.
- 5.3.1 Transfers of Value relating to retired or non-practising HCPs in the UK shall be disclosed on an aggregate basis (irrespective whether consent is given or not) in order to safeguard privacy through avoidance of the requirement of mandatory disclosure of the HCP's address.

- 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 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 Transfer of Value disclosures made for a period of at least five (5) years (or otherwise in accordance with applicable data protection laws).
- 5.7 In accordance with local disclosure requirements each Disclosure by country will be disclosed in one single currency. To minimise exchange rate differences the Currency used will be clearly stated on the published template and will depend on the number of payments made during the period and most commonly used currency during the period. Exchange rates used for this period can be found in Appendix 3

6. Donations in 2022

6.1 Donations

6.1.1 **Staff Volunteering – Mid and South Essex NHS Foundation Trust - GBP 0.00**

After a government call for volunteers for local Hospitals and Covid centres during the pandemic, we as a company fully supported staff who wished to step forward and volunteer in their own time and within working hours. During 2022 our volunteer staff helped with managing Wellbeing Hubs for NHS staff and supporting booking appointments, travel and administrative tasks for the flu and covid vaccination campaigns, all while completing their normal duties to the company.

6.1.2 **Zhytomyr Humanitarian Hub - Ukraine Embassy – JPY 13,980,300**

Mitsubishi Tanabe Pharma Corporation was contacted via JPMA (Japan Pharmaceutical Manufacturers Association) with a request from the Ukraine Embassy in March 2022, this request was for a donation of selected medicinal products based on a drug list provided and for the purpose of providing healthcare and humanitarian support to those in and around Ukraine and affected by the current situation. In June 2022, MTPC provided a charity contribution of the requested 11 medicinal products.

Appendix 1

Research and Development Transfer of Value

Type	Description	Collation / Disclosure	
non-clinical studies		aggregate	by country
Non-interventional studies		aggregate	by country
Phase I clinical studies	<ul style="list-style-type: none"> • payments made to clinical research organisations on a purely commercial basis for phase I services are outside of the scope of these disclosure requirements; • payments made directly / indirectly to HCOs/HCP's (for example for referral services or academic Phase I studies) are within scope. 	aggregate	by country
Payments made to investigative site (institutions, investigators and other ancillary providers) for Phase II – IV Clinical Studies	<p>Typically contracted by CROs and managed as third-party providers, it is nevertheless MTPG Company's responsibility to disclose transfers of value to investigative sites, including for example:</p> <ul style="list-style-type: none"> • Clinical Trial Agreements (where payment is to the institution) • Institution and Investigator Agreements • Laboratory, Radiology and other ancillary services provided within the institution where they receive payment directly. • Technical training for clinical research (e.g., training on lab procedures, equipment and systems) 	aggregate	by country
Key Opinion Leaders (KOLs)	Typically, under either a Speaker Agreement or a Consultancy Agreement, KOLs may provide a wide range of consultancy services, from input into development of a compound, to discussing its development and benefits with MTPC/MTPE or to external events.	aggregate	by country
Advisory Board Members		aggregate	by country
Data Safety Management Board (DSMB) Members		aggregate	by country
Steering Committee Members		aggregate	by country

Non-Research and Development Transfers of Value

		Examples of type of Transfer of Value		Collation / Disclosure
		HCO	HCP	
Hospital departmental meetings (breakfast / lunchtime)	<p>Hosted by MTPG Company at individual hospitals to provide educational updates / promotion of MTPG Product.</p> <p>May involve an expert presentation from a KAM. Typically attended by individual hospital staff only.</p>	<ul style="list-style-type: none"> • Donation / Grant as for the benefit of the HCO as a Transfer of Value. 	<ul style="list-style-type: none"> • Services / Consultancy – KAM / Speaker 	individual
Local Speaker Meeting	<p>Hosted by MTPG Company at within a hospital or other central venue to provide educational information / promotion of MTPG Product.</p> <p>Involved an expert presentation Typically attended by a number of healthcare professionals from different hospitals.</p>		<ul style="list-style-type: none"> • Services / Consultancy – KAM / Speaker • Contribution to costs related to an Event if relevant. 	individual
Exhibition	<p>Where MTPG Company pays an external party for exhibition space to promote MTPG Product at an industry Exhibition. Attended by healthcare professionals.</p>	<ul style="list-style-type: none"> • Possible Sponsorship where exhibition is held in a hospital. 	<ul style="list-style-type: none"> • Contribution to costs related to an Event if relevant. 	individual
National Congress / Symposium	<ul style="list-style-type: none"> • Attendees will be either nationwide or international • Educational / promotional purpose. 	<ul style="list-style-type: none"> • Possible Sponsorship, for example exhibition space or speaker symposium. 	<ul style="list-style-type: none"> • Contribution to costs related to an Event if relevant. 	individual
Speakers / Consultants	<ul style="list-style-type: none"> • HCP engaged under a Speaker / Consultancy Agreement to present at any of the above on Company Product. • KOLs • Advisory Board Members 	<ul style="list-style-type: none"> • Contracted Services 	<ul style="list-style-type: none"> • Contracted Services 	individual

Appendix 2

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 s.28 AKG Code of Conduct dated 22 July 2014
Belgium	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Bulgaria	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Croatia	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Cyprus	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Czech Republic	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Denmark	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Estonia	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
France	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Finland	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
*Germany	MTPD / MTPE	English / German	MTPE Website in accordance with AKG Transparency Rule s.28 AKG Code of Conduct dated 22 July 2014
Greece	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Hungary	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Ireland	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Italy	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Latvia	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Lithuania	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Malta	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Netherlands	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Norway	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Poland	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Portugal	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Romania	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019

Serbia	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Slovakia	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Slovenia	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Spain	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
Sweden	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 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 2019
Ukraine	MTPE	English	MTPE Website in accordance with EFPIA Code of Practice, Chapter 5 2019
*United Kingdom	MTPE	English	Disclosure UK platform & MTPE Website in accordance with ABPI Code of Practice, Clause 28 2021

*Locations of established MTPG companies

Appendix 3

Exchange rates used during the 2022 period.

Original Currency	Conversion Currency	Exchange Rate Used
Euro (EUR)	British Pounds (GBP)	0.8849
United States Dollars (USD)	Euro (EUR)	1.0667
Euro (EUR)	Swiss Franc (CHF)	0.9851
Polish Zloty (PLN)	Euro (EUR)	4.6745
Euro (EUR)	Swedish Krona (SEK)	11.1533
Norway Krone (NOK)	Euro (EUR)	10.5446
Ukraine Hryvnia (UAH)	Euro (EUR)	39.3932
Russian Rouble (RUB)	Euro (EUR)	78.3992
Japanese Yen (JPY)	Euro (EUR)	137.76