

## Mitsubishi Tanabe Pharma Group Methodology

### Transfers of Value to Healthcare Professionals (HCP) and Healthcare Organisations (HCO) in Europe

#### 1. Introduction

- 1.1 Under the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations, 2014 (**EFPIA HCP/HCO Disclosure Code**) 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 point of contact with regard to this guidance and enforcement of this process is Dr Martin Davies, MTPE Senior Vice President. The deputies are Mr Kazutaka Maeda, General Manager of Corporate Management and Ms Ashley McGurl, Senior Accounts Assistant.

#### 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 HCP Code:** The EFPIA Code on the Promotion of Prescription-only Medicines to, and interactions with, Healthcare Professionals, 2014.
- 2.3 **EFPIA PO Code:** The EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations, 2011.
- 2.4 **Europe:** Under the EFPIA HCP/HCO Disclosure Code means 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	Switzerland	Turkey	Ukraine
United Kingdom			

- 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 or sponsored by or on behalf of a MTPG Company.
- 2.6 **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.
- 2.7 **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.
- 2.8 **MTPC** means Mitsubishi Tanabe Pharma Corporation and its Affiliates – including NeuroDerm (purchased by MTPC on 18<sup>th</sup> October 2017) and Medicago.
- 2.9 **MTHA** means Mitsubishi Tanabe Holdings America and its Affiliates.
- 2.10 **MTPE** means Mitsubishi Tanabe Pharma Europe Ltd and its Affiliates.
- 2.11 **MTPD** means Mitsubishi Tanabe Pharma Deutschland and its Affiliates.
- 2.12 **MTPG Company** means MTPC, MTHA, MTPE and MTPD.
- 2.13 **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 an 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)	<b>Donations and Grants</b>	<p>May be made in cash, in kind or otherwise and are made to institutions, organisations or associations that are comprised of healthcare professionals and/or that provide healthcare or conduct research (that are not otherwise covered by either the EFPIA HCP Code or the EFPIA PO Code) and <b>may only be made if:</b></p> <ul style="list-style-type: none"> <li>• they are made for the purpose of supporting healthcare or research;</li> <li>• they are documented and kept on record by the donor/grantor; and</li> <li>• they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.</li> </ul> <p>Donations and grants to individual healthcare professionals are not permitted under this definition. Company sponsorship of individual healthcare professionals to attend events is governed by the EFPIA HCP Code.</p>
B)	<b>Contribution to costs related to Events</b>	<p>Contributions made through HCOs or third parties, including sponsorship for HCPs to attend Events, such as:</p> <ul style="list-style-type: none"> <li>• Registration fees;</li> <li>• Sponsorship agreements with HCOs or with third parties appointed by a HCO to manage an Event; and</li> <li>• Travel and accommodation (ref Art 10 of EFPIA HCP Code)</li> </ul>
C)	<b>Fees for Services and Consultancy</b>	<p>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</p>

		Donation/Grant or Contribution to costs related to Events.
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3.1.2 **Healthcare Professionals (HCPs):**

<b>A)</b>	<b>Contribution to costs related to Events</b>	Contributions to HCPs directly or made through HCOs for the benefit of HCPs, related to Events, including: <ul style="list-style-type: none"> <li>● Registration fees; and</li> <li>● Travel and accommodation (ref Art 10 of EFPIA HCP Code)</li> </ul>
<b>B)</b>	<b>Fees for Services and Consultancy</b>	Transfers of Value resulting from or related to agreements between MTPG Company and HCPs under which HCPs provide any type of services to MTPG Company or any other type of funding that is not covered by Contribution to costs related to Events.

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, MTPC 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 (1<sup>st</sup> January – 31<sup>st</sup> December):

4.2.1 direct transfers of value that its 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 by 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 Corporate Management Department** by no later than 31<sup>st</sup> January of each calendar year.

## 5. Disclosure

- 5.1 Transfers of Value are publically 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.
- 5.4 Disclosure will be made via the MTPE website which is publically accessible (<http://www.mt-pharma-eu.com>) 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 30<sup>th</sup> June of each calendar year.
- 5.5 Transfers of Value disclosed in accordance with this policy will remain publically accessible in accordance with country requirements for a period of three (3) years following disclosure.
- 5.6 MTPE Head of Legal Affairs 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).

## 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"> <li>• payments made to clinical research organisations on a purely commercial basis for phase I services are outside of the scope of these disclosure requirements;</li> <li>• payments made directly / indirectly to HCOs/HCP's (for example for referral services or academic Phase I studies) are within scope.</li> </ul>	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"> <li>• Clinical Trial Agreements (where payment is to the institution)</li> <li>• Institution and Investigator Agreements</li> <li>• Laboratory, Radiology and other ancillary services provided within the institution where they receive payment directly.</li> <li>• Technical training for clinical research (eg, training on lab procedures, equipment and systems)</li> </ul>	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	
<b>Hospital departmental meetings ( breakfast / lunchtime )</b>	Hosted by MTPG Company at individual hospitals to provide educational updates / promotion of MTPG Product.  May involve an expert presentation from a KAM. Typically attended by individual hospital staff only.	<ul style="list-style-type: none"> <li>• Donation / Grant as for the benefit of the HCO as a Transfer of Value.</li> </ul>	<ul style="list-style-type: none"> <li>• Services / Consultancy – KAM / Speaker</li> </ul>	individual
<b>Local Speaker Meeting</b>	Hosted by MTPG Company at within a hospital or other central venue to provide educational information / promotion of MTPG Product.  Involved an expert presentation Typically attended by a number of healthcare professionals from different hospitals.		<ul style="list-style-type: none"> <li>• Services / Consultancy – KAM / Speaker</li> <li>• Contribution to costs related to an Event if relevant.</li> </ul>	individual
<b>Exhibition</b>	Where MTPG Company pays an external party for exhibition space to promote MTPG Product at an industry Exhibition. Attended by healthcare professionals.	<ul style="list-style-type: none"> <li>• Possible Sponsorship where exhibition is held in a hospital.</li> </ul>	<ul style="list-style-type: none"> <li>• Contribution to costs related to an Event if relevant.</li> </ul>	individual
<b>National Congress / Symposium</b>	<ul style="list-style-type: none"> <li>• Attendees will be either nationwide or international</li> <li>• Educational / promotional purpose.</li> </ul>	<ul style="list-style-type: none"> <li>• Possible Sponsorship, for example exhibition space or speaker symposium.</li> </ul>	<ul style="list-style-type: none"> <li>• Contribution to costs related to an Event if relevant.</li> </ul>	individual
<b>Speakers / Consultants</b>	<ul style="list-style-type: none"> <li>• HCP engaged under a Speaker / Consultancy Agreement to present at any of the above on Company Product.</li> <li>• KOLs</li> <li>• Advisory Board Members</li> </ul>	<ul style="list-style-type: none"> <li>• Consultancy / Services</li> </ul>	<ul style="list-style-type: none"> <li>• Consultancy / Services</li> </ul>	individual



## Appendix 2

### MTPG Methods of Disclosure on a Country by Country Basis

Country	MTPG Company Responsible for Disclosure	Language	Location of Disclosure
<b>Austria</b>	MTPE	English	MTPE Website
<b>Belgium</b>	MTPE	English	MTPE Website
<b>Bulgaria</b>	MTPE	English	MTPE Website
<b>Croatia</b>	MTPE	English	MTPE Website
<b>Cyprus</b>	MTPE	English	MTPE Website
<b>Czech Republic</b>	MTPE	English	MTPE Website
<b>Denmark</b>	MTPE	English	MTPE Website
<b>Estonia</b>	MTPE	English	MTPE Website
<b>France</b>	MTPE	English	MTPE Website
<b>Finland</b>	MTPE	English	MTPE Website
<b>*Germany</b>	MTPD / MTPE	English / German	MTPE Website in accordance with AKG Transparency Rule s.28 AKG Code of Conduct dated 22 July 2014
<b>Greece</b>	MTPE	English	MTPE Website
<b>Hungary</b>	MTPE	English	MTPE Website
<b>Ireland</b>	MTPE	English	MTPE Website
<b>Italy</b>	MTPE	English	MTPE Website
<b>Latvia</b>	MTPE	English	MTPE Website
<b>Lithuania</b>	MTPE	English	MTPE Website
<b>Malta</b>	MTPE	English	MTPE Website
<b>Netherlands</b>	MTPE	English	MTPE Website
<b>Norway</b>	MTPE	English	MTPE Website
<b>Poland</b>	MTPE	English	MTPE Website
<b>Portugal</b>	MTPE	English	MTPE Website
<b>Romania</b>	MTPE	English	MTPE Website
<b>Serbia</b>	MTPE	English	MTPE Website
<b>Slovakia</b>	MTPE	English	MTPE Website
<b>Slovenia</b>	MTPE	English	MTPE Website
<b>Spain</b>	MTPE	English	MTPE Website
<b>Sweden</b>	MTPE	English	MTPE Website
<b>Switzerland</b>	MTPE	English	MTPE Website
<b>Turkey</b>	MTPE	English	MTPE Website
<b>Ukraine</b>	MTPE	English	MTPE Website
<b>*United Kingdom</b>	MTPE	English	via ABPI central platform, no later than the last working day of March. and MTPE Website in accordance with ABPI - Code of Practice for the Pharmaceutical Industry 2015

\*established MTPG companies