Mitsubishi Tanabe Pharma Group Methodology

Transfers of Value to Members of the Public in the United Kingdom

1. Introduction

- Under the Association of the British Pharmaceutical Industry (ABPI) together with the Prescription Medicines Code of Practice Authority (PMCPA) Code of Practice 2021 pharmaceutical companies are required to document and disclose Transfers of Value made to Members of the Public, including Patients & Journalists (MoP) on an annual basis.
- 1.2 This guidance is applicable to and documents the process to be followed for the disclosure of Contracted Services provided to members of by MTPG Companies to MoPs in the United Kingdom.
- 1.3 It is the responsibility of the relevant MTPG staff to determine that the proposed Transfer of Value to a MoP 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.

ABPI Code: The Association of the British Pharmaceutical Industry Code of Practice 2021 – Clause 30 in accordance with Clause 24.

- 2.2 MTPC means Mitsubishi Tanabe Pharma Corporation and its Affiliates including NeuroDerm and Medicago.
- 2.3 MTHA means Mitsubishi Tanabe Holdings America, Inc. and its Affiliates.
- 2.4 MTPE means Mitsubishi Tanabe Pharma Europe Ltd and its Affiliates.
- 2.5 MTPD means Mitsubishi Tanabe Pharma GmbH and its Affiliates.
- 2.6 **MTPG Company** means MTPC, MTHA, MTPE and MTPD.
- 2.7 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 Members of the Public (MoPs):

Contracted Services	These services include speaking at meetings, assistance with training, writing articles and/or publications, participating in advisory boards, advising on the design etc of clinical trials and participating in market research
	where such participation involves remuneration and/or travel.

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 MoPs;
 - 4.2.2 direct ToV to MoPs 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 MoP should be listed individually on the form, even if there are multiple ToV's to the same MoP during the period.
 - 4.2.5 Fees & Expenses should be listed separately.
 - 4.2.6 A description of the types of services should be provided that is sufficiently complete to enable the reader to understand the nature of the services provided.

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 MoP 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
 - Each Project Manager managing relevant third party relationships has overall responsibility for ensuring completion and return of the Transfer of Value - MoP Form by that third party.
- 4.3.3 Completed Forms must be submitted to <u>MTPE's Finance Department</u> 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 MoPs: in accordance with the disclosure requirements of the association where the registered place of business is located.
 - 5.1.2 Data will only be published if a ToV has taken place during the period.
- 5.2 Each MoP 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
 - 5.2.2 The monetary value for each out of pocket expenses reimbursed
- 5.3 Where MTPG members have engaged with a MoP 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 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.