

## PATIENT ORGANISATIONS DISCLOSURE: EFPIA METHODOLOGICAL NOTE

### 1. ASTELLAS'S COMMITMENT

- 1.1 Astellas is a member company of the European Federation of Pharmaceutical Industries and Associations (“EFPIA”). The EFPIA Code (the “EFPIA Code”) requires all member companies to document and disclose certain Transfers of Value they make, directly or indirectly, to or for the benefit of, Patient Organisations (“POs”) (“Disclosures”).
- 1.2 Astellas discloses all Transfers of Value to POs in accordance with its commitment to the EFPIA Code.
- 1.3 This note summarises the methodologies used by Astellas in preparing Patient Organisations Methodological Note pursuant to Chapter 5 of the EFPIA Code of Practice.

### 2. DEFINITIONS

- 2.1 The EFPIA Code defines the following terms:

- **Patient Organisation (PO):** non-for-profit legal person/entity (including the umbrella organisation to which it belongs), mainly composed of patients and/or caregivers, 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 in Europe
- **Patient Organisation Representative:** is a person who is mandated to represent and express the collective views of a PO on a specific issue or disease area.
- **“Transfer of Value (ToV)”:** Direct and indirect ToV, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of POM exclusively for human use. Direct ToVs are those made directly by Astellas for the benefit of a Recipient. Indirect ToVs are those made on behalf of Astellas for the benefit of a Recipient, or those made through a Third Party and where Astellas knows or can identify the Recipient that will benefit from the Transfer of Value.

2.2 Disclosures must remain in the public domain for a minimum of three years and Astellas will document all Disclosures and retain the records for at least seven years.

### **3. PATIENT ORGANISATION DISCLOSURE**

3.1 Astellas makes its disclosures at a European level by country on an annual basis covering the calendar year. Each country report will include the following:

3.1.1 A description of the nature of the support or services provided

3.1.2 For Support:

- The monetary value of financial support and of invoiced costs.
- The non-monetary benefit that the PO receives when the non-financial support cannot be assigned to a meaningful monetary value.

3.1.3 For Contracted Services:

- The total amount paid per PO over the Reporting Period.

### **4. COUNTRY OF DISCLOSURE**

Astellas discloses Transfers of Value based on where the PO is registered.

### **5. MULTI-YEAR CONTRACTS**

Where a contract for any Transfer of Value listed in Section 3.1.3, runs for more than one year, Astellas will record Transfers of Value relating to that contract in the year the Transfer of Value was made (which may be different to the year in which the contract was agreed).