Sunovion Pharmaceuticals Europe Ltd. Disclosures of payment to Healthcare Professionals Methodological Note for 2020 filing 30.03.2021

Sunovion Pharmaceuticals Europe Ltd. (Sunovion or the "Company") has prepared this document to outline the Company's interpretations and assumptions made and methodologies used in complying with the requirements to disclose payments to Healthcare Professionals (HCPs), Healthcare Organisations (HCOs) and Other Relevant Decision Makers (ORDMs) under the Code of Practice 2016 administered by the Prescription Medicines Code of Practice Authority (PMCPA) and the Code on disclosure of transfer of value from pharmaceutical companies to healthcare professionals and healthcare organisations adopted by the European Federation of Pharmaceutical Industries and Associations (EFPIA).

This document only applies to the Disclosures of Payments submitted by the Company for the corresponding year of this Methodological Note – subsequent documents related to future submissions may or may not include, at the discretion of the Company, changes and/or updated assumptions, interpretations and methodologies.

As a general matter, Sunovion will file disclosure reports separately from its affiliates, including its parent company Sunovion Pharmaceuticals Inc. (SPI) and ultimate parent company Sumitomo Dainippon Pharma Co., Ltd, ("DSP") and other subsidiaries of the parent company. However, the Company's report will include, where applicable, Transfers of Value by members of the group to HCPs, HCOs and ORDMs in Europe. This document addresses the Company's assumptions only.

Top level assumptions:

Generally, all data related to payments and Transfers of Value is captured and reported on an "accruals basis" where Sunovion has directly or indirectly made the payment or made the Transfer of Value. However, payments made after December 31, 2020 for events that took place in 2020 will be included in the 2021 report. The Transfer of Value will be recognized based on the payment date.

Sunovion has taken reasonable efforts to validate all data included in the submission to ensure all data elements are collected, and that the data elements are current, accurate and complete (including that they accurately reflect the interaction that took place, e.g., that the value reported is consistent with the value on a related receipt).

Definitions:

Europe: includes all European Union countries and other countries with a trade association that is a member of EFPIA i.e. Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and United Kingdom

Healthcare Professional: any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCP includes:

(i) Any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and

(ii) Any employee of a member company whose primary occupation is that of a practising HCP but excludes

(x) all other employees of a member company and (y) a wholesaler or distributor of medicinal product

Healthcare Organisations: Either a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in Europe or an organisation through which one or more health professionals or other relevant decision makers provide services.

Other Relevant Decision Makers: are comprised of those individuals who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who are not healthcare professionals.

Transfers of Value: Direct and indirect Transfers of Value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of Prescription Only Medicinal Products for human use. Direct Transfers of Value are those made directly by Company for the benefit of the Recipient. Indirect Transfers of Value are those made on behalf of the Company for the benefit of the Recipient, or Transfers of Value made through an intermediate and there the Company knows and can identify the HCP/HCO that will benefit from the Transfer of Value.

Recipient: any HCP or HCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Europe.

Data gathering process:

There are two sources of input to the final report:

- Accounting data: Accounting Database is used to record payments to HCPs, HCOs and ORDMs into specifically allocated Nominal Ledger codes to capture honoraria, expenses, sponsorships and other qualifying transactions.
- General Payments and Research data collection templates: these templates are used for collecting all other transactions from third party vendors, affiliates or employees who are processing this data on the Company's behalf. Sunovion customises each data collection template (from a larger Master Template) to provide only those fields that need to be reported by the employee or vendor responsible for submitting the data.

Nature of Payment or Transfer of Value:

There are several categories of disclosures specified in the regulations which have been used for classification of transactions.

	Joint Working
	Donations and Grants to HCOs and Benefits in Kind to HCOs
	Sponsorship agreements with HCOs/third parties appointed by HCPs to manage an Event

	Registration Fees for Events
	Travel and Accommodation for Events
	Fees for service and Consultancy
	Related Expenses agreed in the fees for service or consultancy contract
	Research & Development payments

Definition of Transfers of Value:

Joint Working

Situations where, for the benefit of patients, one or more pharmaceutical company and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery.

Donations and Grants to HCOs and Benefits in Kind to HCOs

Donation
Financial support for an institution, non-profit or organisation, typically for general support rather than a specific purpose, with no influence or control exerted by the Company.

Grant
Financial support for an institution or organisation, typically for a specific purpose, with no influence control exerted by the Company.

Benefit in Kind
Transfers of value in kind or pecuniary form to an institution or organisation with no influence or control exerted by the Company.

Sponsorship agreements with HCOs/third parties appointed by HCPs to manage an Event
Support for a specific event, activity or item which is organised and or produced by, or for, a third party. This may include financial support, goods or services.

Registration Fees for Events
Support in the form of payment of registration fees for the events organised and or produced for by the Company or by third party, both inside and outside the UK.

Travel and Accommodation for Events
Support in the form of payment of travel and accommodation for the events organised and or produced by the Company or by the third party, both inside and outside the UK.

Fees for service and consultancy
Fees paid to HCPs and ORDMs, or to their employees on their behalf for certain services rendered, such as chairing and speaking at meetings, assistance with training and participation in advisory boards etc.

Related Expenses agreed in the fees for service or consultancy contract
Expenses paid to HCPs and ORDMs, or to their employees on their behalf in relation to the certain services rendered, such as chairing and speaking at meetings, assistance with training and participation in advisory boards etc.

Research & Development payments

ToVs to healthcare professionals or healthcare organisations related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Directive 2001120/EC9); 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, healthcare professionals specifically for the study

Non-monetary transfers of value:

Company uses solely monetary transfers of value: cash or cash equivalent.

Optional data:

The Company does not expect to submit any optional information fields.

Dispute Resolution

The Company will attempt to resolve disputes with Recipients. Upon notification that a dispute has been initiated, the Company will review and attempt to resolve each dispute on an individual basis. If a resolution cannot be reached, the reported Transfer of Value will be moved into the aggregate section of the database.

Individual disclosures – HCPs and ORDMs:

For HCPs/ORDMs who have given their consent to individual, named disclosure, the Company will collect and disclose the following detail:

- Title, first name and last name of HCP (mandatory), any other initial is optional
- Speciality and /or the role. Where known (optional)
- City and country of principle practice (mandatory)
- Institution name, address and postcode (mandatory)
- Email address, where known (optional)
- Third party database ID (optional)
- Annual total amount of transfers of value broken down by the following mandatory category:
  - Registration fees for events
  - Travel and accommodation for events
  - Consultancy fees
  - Expenses agreed in the fee for services or consultancy contract.

Aggregate Disclosures – HCPs and ORDMs:

For HCPs/ORDMs who have not given their consent to individual named disclosure the company will disclose the following details only:

- Aggregated annual total amount of Transfers of Value for all such HCPs/ORDMs
- Number of HCPs/ORDMs whose Transfers of Value data is included in the aggregate figure
- Proportion of total Transfers of Value to HCPs/ORDMs that the aggregate amount represents, expressed as a percentage of per category spend for all recipients individual and aggregate.

HCOs

For HCOs the data collection template will record and disclose details of transfers of value made on a per activity basis.

Privacy Laws and Consent to Disclose

Before payment to HCPS/ORDMs the Company asks them to confirm their consent for the data to be publicly disclosed. Only those individuals that gave their consent are disclosed as individual HCPS/ORDMs. If the

individual does not give a consent to disclose, the Company will ensure that Transfers of Value made to that individual are only disclosed in aggregate.

The Company will retain evidence of consent for 5 years

Country specific considerations/cross border payments:

For the countries where the Company has a Commercial presence, it discloses payments to HCPs according to the local country Code in which they operate namely Norway, Sweden, Finland, The Netherlands, Denmark and Switzerland. For all other European Countries, the Company opts to disclose the payments to European HCPs through UK database due to the limited number of transactions.

Affiliates:

The Company collects information from its affiliates and includes relevant transactions to HCPs and HCOs in Europe into Company disclosures.

Tax and VAT considerations

Company reports payments free of Value Added Tax or any other applicable taxes.

Currency Exchange

The Company applies historical exchange rates over the reporting period to all transaction originating in foreign currency (non-GBP transactions).