**Amarin –Transparency Disclosure Methodology Statement**

The “ABPI” Code of Practice requires pharmaceutical companies to document and disclose annually certain Transfers of Value (“ToVs”) they make, directly or indirectly, to or for the benefit of, healthcare professional (“HCPs”), other relevant decisions makers (“ORMDs”) healthcare organisations (“HCOs”) and payments made to patient organisations (“POs”) and the public, including patients and journalists.

Amarin is committed to comply with the ABPI transparency requirement around interactions with HCPs, HCOs and POs, including the nature and scope of our ToVs. Amarin discloses these in accordance with the relevant data privacy and transparency disclosure legislation.

This note describes the methodologies and business rules used by Amarin to meet its reporting and disclosure obligations in line with the ABPI Code of Practice Transparency Disclosure legislations.

Amarin Pharmaceuticals Ireland Limited and its affiliates (“Amarin”) interact with Healthcare Professionals (“HCPs”), Healthcare Organisations (“HCOs”) and Patient Organisations (“PO”) and members of the public to obtain or provide scientific or educational knowledge or to support medical research in the interest of patients.

Amarin is committed to upholding high ethical standards when interacting with HCPs and HCOs POs and members of the public. As part of this commitment and in accordance with applicable industry standards and relevant legislation (“Transparency Disclosure Rules”), Amarin and its affiliates are required to disclose payments made to healthcare professionals, healthcare organisations, POs and members of the public.

Amarin has established a Transparency Reporting Process in line with the ABPI Code of Practice in the UK.

# **Definitions:**

* **ABPI**: The Association of the British Pharmaceutical Industry trade organisation representing the research based pharmaceutical industry operating in the United Kingdom.
* **“Contracted Services”:** Any HCPs, ORDMS, HCOs, POs, individuals representing patient organisations, and members of the public, including patients and journalists used as consultants and advisors (in groups or individually) for services such as speaking at and chairing meetings, involvement in medical/ scientific studies, clinical trials or training services, writing articles and/or publications, participation at advisory board meetings, and participation in market research where such participation may involve remuneration and/or hospitality
* **“Contribution to costs related to events”:** in relation to the disclosure of transfers of value means providing or covering the costs of travel, accommodation and/or registration fees to support the attendance of an individual to an event organised or created by a company and/or independent organisation. When providing sponsorship of events/meetings to organisations, associations etc. such contributions may include costs for subsistence (food and drink)
* **“Collaborative Working”:** Pharmaceutical companies working with other organisations to deliver initiatives which either enhance patient care or are for the benefit of patients or alternatively benefit the National Health Service (NHS) and, as a minimum, maintain patient care.
* **“Events":** all professional, promotional, scientific and educational 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 noninterventional studies) organised or sponsored by or on behalf of a company.
* **“Grants and Donations”:** Donations and grants are 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 to the benefit of Amarin in return. In general, donations are physical items, services or benefits-in-kind which may be offered or requested. Grants are the provision of funds.
* **“Healthcare Professional (HCP)”**: Any member of the medical, dental, pharmacy or nursing profession and any other person who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine. In relation to the annual disclosure of transfers of value, the term also includes any employee of a pharmaceutical company whose primary occupation is that of a practising health professional. If an HCP has set up a private company, as a sole director, they will be considered an HCP for disclosure purposes.
* **“Healthcare Organisation (HCO)”:** 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.
* **“Hospitality”:** is limited to travel, subsistence (food and drink), accommodation and genuine registration fees extended in connection with events/meetings.
* **“Other relevant decision maker (ORDM)”** Includes someone with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who is not a health professional.
* **“Patient Organisation (PO)”**: An organisation mainly comprising of patients and/or caregivers or any user organisation such as a disability organisation, carer or relative organisation and consumer organisation that represents and/or supports the needs of patients and/or caregivers.
* **“Individuals representing patient organisations”:** Any person who is mandated to represent and express the views of a patient organisation.
* **“Members of the public”:** Any ToV made directly by Amarin or via a third party on its behalf to members of the public including individual patients, carers and journalists is disclosed in aggregate on Amarin corporate website annually.
* **“Sponsorship”:** a contribution, financial or otherwise, in whole or in part provided by or on behalf of a company, towards an activity (including an event/meeting or material) performed, organised, created etc by a healthcare organisation, patient organisation or other independent organisation.
* **“Support”:** provision of a financial contribution, in whole or in part, whether paid directly or indirectly to individual health professionals or other relevant decision makers to attend events/meetings.
* **“Transfer of Values (TOV)”:** A direct or indirect transfer of value, whether in cash, in-kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines.
	+ A direct transfer of value is one made directly by a company for the benefit of a recipient.
	+ An indirect transfer of value is one made on behalf of a company for the benefit of a recipient or through an intermediate and where the company knows or can identify the recipient that will benefit from the transfer of value.
	+ In-kind: any significant non-monetary support provided to benefitting patient organizations.
	+ Cross-border ToV: ToV to a patient organization where a non-UK Amarin entity or intermediary on behalf of Amarin has provided the funding and the patient organisation is registered at an address in the UK.
	+ ToV to an individual patient, who does not represent or is not hired through a patient organization, is disclosed in aggregate together with other members of the public including carers and journalists, for example.

Any ToV related to HCP’s providing Consulting services must be of Fair Market Value (“FMV”), ensuring a high level of objectivity in the rate determination process and removing any potential bias.

* **“Recipients”:** Any HCP, HCO, PO or member of the public receiving a ToV from Amarin or on Amarin’s behalf whose, as applicable, primary practice, principal professional address or place of incorporation or resides is in the United Kingdom.
* **“Research and Development (R&D)”:** HCP/HCO transfers of value that relate to the planning and conduct of:
	+ Non-clinical studies (as defined in OECD Principles on Good Laboratory Practice).
	+ Clinical trials (as defined in Regulation 536/2014)
	+ 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. This also includes investigator sponsored research (ISRs).

# **Transfers of Value**

ToVs made directly to an HCP/HCO/PO and members of the public or indirectly on behalf of Amarin through a third party will be disclosed within this report.

ToVs are reported based on payment date or transfer of value date (e.g., the date a flight was taken).

HCP disclosure will be made based on the named individual if consent has been obtained; refer below for further information on our consent methodology.

Research and development will be disclosed in aggregate for all disclosure reports.

# **Cross-border Payments**

All payments made to HCPs and HCOs from outside the UK are tracked and managed centrally by Amarin. Amarin are able to track all external payments made to patient organisations and individual members of the public within the UK.

# **Consent**

Data protection laws and transparency rules require Amarin to collect consent from HCPs to disclose ToVs against named individuals. Amarin will contact HCPs to seek their consent to disclose all interactions entered into with Amarin. Where consent has not been granted, Amarin will disclose ToVs in aggregate and will not publish against the named individual.

HCPs have the right to withdraw consent at any time. If Amarin receives such a withdrawal of consent, Amarin will, within a reasonable period, move the relevant ToV data into the aggregate category.

# **Pre-disclosure validation**

Amarin has made reasonable efforts to ensure completeness and accuracy of our disclosable spend and has worked closely with third party vendors and agencies to collect relevant information. In order to maintain transparency in our reporting, Amarin has provided HCPs involved in non-R&D activities, a statement for review and validation prior to Amarin’s transparency disclosure reports. If no response has been received to correct the data in the statement, Amarin has assumed this is accurate for disclosure purposes.

# **Country of disclosure**

Amarin discloses ToVs based on the HCPs principal place of practice. If an HCP operates in more than one country, Amarin will select one country to be the primary principal place of practice and disclose in that country.

# **Currency**

Amarin discloses ToVs to HCPs, HCOs, POs and members of the public in GBP currency. Where ToVs are made in another currency, the invoice amount will be converted into GBP currency using the exchange rate. Amounts disclosed may therefore vary slightly from the exact amounts paid to HCPs, HCOs and POs.

# **Tax**

Amarin discloses all ToVs excluding VAT and other applicable taxes unless required by law for inclusion.

# **Timing & multi-year contracts**

Amarin discloses all ToVs made between 1 January and 31 December by the last Working Day of March, based on local requirements. Where an interaction with an HCP, HCO, PO or member of the public runs for more than one year, Amarin will disclose ToVs made in the year of payment or transfer.

# **Cancellations and non-participation**

ToVs will only be disclosed where the benefit has been received. In the event of a cancellation or where an HCP/HCO/PO does not receive the benefit due to non-participation, Amarin will not disclose ToVs against the HCP/HCO/PO.

# **Disclosure and Document Retention Periods**

Amarin will maintain public disclosures for a minimum of three years and will retain records for at least five years after the end of the calendar year to which they relate.