



## **2021 Methodological Note – Transparency Declarations under ABPI**

### **I. Introduction**

In 2020, Aimmune Therapeutics, Inc. was acquired by Nestlé and became Aimmune Therapeutics, a Nestlé Health Science company, which is a stand-alone business unit that manages Nestlé Health Science’s global pharmaceutical business. Aimmune Therapeutics, and its affiliates (i.e. those affiliates that form part of the pharmaceutical business) (collectively “Aimmune”), are committed to ensuring the nature and scope of transfers of value (ToV) provided to healthcare professionals (HCPs), healthcare organisations (HCOs), and other relevant decision makers (ORDMs) are clear and transparent to the public. Therefore, Aimmune has published applicable ToV provided directly or indirectly to HCPs, HCOs, or ORDMs between 15 July 2021 and 31 December 2021, which is the period in the 2021 calendar year that Aimmune Therapeutics UK Limited agreed to comply with the ABPI Code of Practice for the Pharmaceutical Industry 2021 (the “ABPI Code”) and accept the jurisdiction of the PMCPA as a non-member company.

This methodological note is intended to help readers understand how Aimmune collected ToV data and prepared reports for disclosure per the guidelines set forth in the ABPI Code.

### **II. Data Collection**

2021 is the first year for which Aimmune is publishing a report using the DisclosureUK platform. For this first reporting year, Aimmune is disclosing applicable ToV that were provided on or after 15 July 2021, based upon the Reporting Date (as defined in section X below). In subsequent years, Aimmune will disclose all applicable ToV made during the full calendar year.

Aimmune uses a combination of automated systems and manual data collection processes to capture information relating to applicable ToV to HCPs, HCOs, and ORDMs from internal sources and external third parties who make ToV to HCPs/HCOs/ORDMs on behalf of Aimmune. The published information reflects our good faith and best efforts to comply with the disclosure provisions of the ABPI Code.

Despite our best efforts to accurately disclose ToV, if we become aware of a disclosure that appears to be inexact or incomplete, we will review and amend as needed.

Aimmune does not have any “over the counter” medicines or medical devices; therefore, all ToV relate to prescription-only medicines.

This disclosure data is not to be used for any other purposes beyond providing transparency surrounding engagements with HCPs, HCOs, and ORDMs. Aimmune, when disclosing these ToV declarations, does not grant any form of license or authorisation, either special or general, allowing anyone to access these ToV declarations and their content.

### **III. Definitions**

When preparing our disclosures, we applied the definitions found in the ABPI Code for all applicable terms including, but not limited to, “Healthcare Organisation (HCO),” “Healthcare Professional (HCP),” “Transfers of Value (ToV),” “Research and Development,” “Donation,” “Grant,” and “Sponsorship.”

#### **IV. Categories of Disclosure**

When preparing our disclosures, we applied the standards found in the ABPI Code for all applicable Categories of Disclosure including, but not limited to, “Collaborative Working,” “Donations and Grants to HCOs,” “Contribution to costs of Events,” and “Contracted Services.”

#### **V. Cross-border Transfers of Value**

Cross-border ToV may occur if an Aimmune affiliate provides a ToV to an HCP or HCO whose principal country of practice is different than the location of the Aimmune affiliate (e.g. Aimmune Therapeutics UK Limited may make a payment to a French HCP).

Aimmune will issue one disclosure report for each country showing all ToV made to HCPs, HCOs, and ORDMs in that country, and each report will be published by the relevant Aimmune affiliate for that country and in the manner prescribed by the country (e.g. national platform, company website).

Aimmune discloses ToV based upon the recipient HCP’s principal country of practice. If an HCP practices in more than one country, Aimmune will disclose all ToV to that HCP in the HCP’s principal country of practice.

#### **VI. Indirect Transfers of Value**

When preparing our disclosures, we included indirect ToV made to HCPs/HCOs/ORDMs as defined in the ABPI Code. These indirect payments may include work commissioned by Aimmune that is then contracted out to an individual HCP. In such cases, Aimmune coordinates with the contracted service agency to obtain all necessary information for preparing our transparency disclosures.

#### **VII. Data Protection and Aggregate Disclosure**

In connection with the collection and processing of HCPs’ personal data, Aimmune complies with all applicable data protection laws. Aimmune requires consent from HCPs prior to publishing their personal data, including details of any ToV provided by Aimmune, unless otherwise specified in an applicable country’s law or regulation regarding transparency.

For ToV in which Aimmune is unable to disclose on an individual basis for legal reasons, including compliance with data protection requirements, Aimmune will disclose on an aggregate basis.

HCPs have the right to withdraw their consent for the individual disclosure of their information at any time. In such cases, any ToV to these individuals will be disclosed on an aggregate basis in a way that does not identify these individuals.

#### **VIII. Currency**

Where payments were made in a currency other than the currency of the country in which the disclosure report is made, the payment amount will be converted to the disclosure currency based upon the exchange rate that was in effect on the date the payment was made.

#### **IX. VAT and Other Tax**

Aimmune reports ToV as net (i.e. without value added tax or withholding tax) unless the collection of net values is not possible through the particular financial system in which the data was collected.

#### **X. Transfer of Value Reporting Date**

Aimmune discloses all ToV based on the date the transfer occurred (the “Reporting Date”) (e.g. date meal was provided) or the check date (e.g. if a contract is signed on 01 November 2020 but the check date for consulting services is 05 August 2021, this payment reporting date will be 05 August 2021 and will be published in the 2021 data disclosure report).

#### **XI. Multi-year Projects**

Where projects run for several years, such as clinical trials, Aimmune will declare the payment amount relevant to the year in which each part of the payment was made. For example, if a project spans 2 calendar years and includes several individual ToV during each year, Aimmune will make two associated disclosures, one for each calendar year showing the value of the transfers made in each specific calendar year.

#### **XII. Market Research**

Market Research payments made to a contracted service agency will not be disclosed if the research is conducted within industry standard principles of market research and the research is either (1) double-blinded or (2) single-blinded where the HCP recipient may know the identity of Aimmune, but Aimmune does not know the identity of the HCP recipient. Any non-blinded Market-Research-related payments (i.e. the identity of the HCP recipient is known to Aimmune) will be disclosed.

#### **XIII. Sponsorships for HCPs to Attend Meetings**

Aimmune may support the attendance of HCPs at educational, scientific meetings. Aimmune will disclose the associated Transfers of Value against the individual attendee. Where costs are not individually itemised (e.g. the cost of a bus transferring a group of HCPs from an airport to a conference venue), the total cost will be split equally between all those receiving the benefit.

Costs declared include transport, registration fees, accommodation, and other forms of hospitality.

#### **XIV. HCP Cancellations and No-Shows**

If an HCP is invited to an event but does not come to such event, any payments made on the date of the event will not be included as a ToV to the HCP who did not attend. However, if there is ToV that is not cancellable or reimbursable (e.g. ToV related to accommodation or transport), this ToV will be included in the relevant transparency declarations.

If an event must be cancelled, cancellation fees are not included in transparency declarations.

#### **XV. Grants to HCOs for Support to Attend Medical Meetings**

HCOs may make requests inviting Aimmune to provide financial support to assist its employees to attend medical meetings. If Aimmune has agreed to such a request, where the payment is associated with named HCPs, this payment is disclosed as ToV to the named individual HCPs. Where Aimmune is not aware of the identities of the individual HCPs receiving the support, the financial support is declared as a ToV to the named HCO.

## **XVI. Contributions to Meetings**

Aimmune will disclose all payments made to HCOs in relation to meetings. This includes direct funding, such as sponsorship fees or the right to host an exhibition stand, and indirect support such as providing a logistics agency or subsidising the cost of registration fees.

## **XVII. Payments to HCOs for Services Provided by Individual HCPs**

Where services for Aimmune are rendered by an HCP on behalf of an HCO (for example, Aimmune enters into a service contract with an HCO and the services are provided by the HCO's employee who is an HCP), the associated fees and expenses paid by Aimmune to the HCO are disclosed as ToV made to the HCO. This is the case unless Aimmune can confirm that the HCP received a benefit from the ToV, either directly from Aimmune or via the HCO (e.g. fees paid to the HCP in connection with the services he/she rendered and/or reimbursement of any related expenses the HCP incurred), in which case Aimmune will disclose those ToV as being transfers to the HCP.

Where Aimmune can identify the HCP and know that the HCO will make the full ToV to the HCP on Aimmune's behalf, the ToV is disclosed as being a ToV to the HCP. Any "administration fee" charged by the HCO will be disclosed as a ToV fee for the service to that organisation. And if the HCP does not receive any additional payment for the service (e.g. because he/she is speaking at a meeting during normal working hours) then the full amount paid by Aimmune will be disclosed against the HCO as a ToV.

## **XVIII. Transfers of Value to Patient Organisations**

Disclosure data for patient organisations is published on our company website per ABPI Code clause 29.1.

If a ToV is associated with an individual HCP working with a PO, then some or all of the funding may be disclosed in two separate disclosure reports – any ToV provided to the HCP will be disclosed against the individual HCP and in the manner required by the ABPI Code; and the total value of the project will be disclosed as a ToV to the PO on Aimmune's website.

Aimmune will disclose all payments made to POs in relation to meetings. This includes any direct funding that Aimmune may provide to a PO, such as sponsorship fees, and any indirect support, such as providing a logistics agency or subsidising the cost of registration fees.