

# **Arvelle Therapeutics International GmbH, a company of Angelini Pharma**

## **Methodology**

**on Disclosure of Transfers of Value to HCPs and  
HCOs as for Farmindustria Code of Conduct**

**Disclosure reporting period: 2021**

## INDEX

<b>1. INTRODUCTION .....</b>	<b>3</b>
<b>2. ARVELLE THERAPEUTICS INTERNATIONAL GMBH – SWITZERLAND TOVS.....</b>	<b>3</b>
Events: details.....	4
<b>3. DISCLOSURE METHODOLOGY .....</b>	<b>5</b>
<b>4. DATA PROTECTION AND CONSENT MANAGEMENT .....</b>	<b>5</b>
HCPs .....	5
HCOs.....	6
<b>5. DEFINITIONS PURSUANT TO FARMINDUSTRIA CODE OF CONDUCT .....</b>	<b>6</b>

## 1. INTRODUCTION

Angelini Pharma is a modern group, projected into the future and always proud of the values that are at the basis of its corporate philosophy.

In February 2021, Angelini Pharma acquired Arvelle Therapeutics; therefore, starting from 2021 ToVs disclosures on, reports include Arvelle Therapeutics ToVs as part of Angelini Pharma Group, in line with local laws, regulations and industry codes.

Angelini Pharma acts with Integrity, Trust, Respect and Transparency as per its core behaviours and it collaborates with various stakeholders including Healthcare Professionals (HCPs), Healthcare Organizations (HCOs), Patient Organizations (POs) on a range of activities in the interest of patients.

Our full commitment to the highest ethics and integrity standards is a cornerstone of our values and our actions; transparency and openness of the interactions with Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs) is one of the key Angelini core behavior, leading our way of conducting ourselves and our business.

Angelini Pharma Headquarter is associated to Farmindustria (Italian Association of Pharmaceutical Companies), member of EFPIA (European Federation of Pharmaceutical Industries and Associations), and therefore all its Affiliates and entities part of the Group are compliant with the disclosure obligation, in line with local laws, regulations, professional requirements and industry codes.

Angelini Pharma Group is committed to ensure that Transparency is respected, demonstrating the integrity of our relationship with HCPs, HCO, disclosing ToVs to HCPs and HCOs.

Arvelle Therapeutics International GmbH is accountable for compliance with Farmindustria regulation for Transfers of Value (ToV) tracking and disclosure, with the support of Global Compliance, because part of Angelini Pharma Group.

ToVs made by Angelini Pharma Group to HCPs/HCOs whose principal address is in Switzerland are published on the website and the report remains in the public domain for a minimum of 3 years after the time such information is first disclosed. This methodological note describes the key aspects and clarifications on the nature of the Transfers of Value included in the disclosure.

## 2. Arvelle Therapeutics International GmbH – Switzerland ToVs

The following table illustrates activities reported according to the specific Farmindustria category and subcategory.

Farmindustria category	Farmindustria subcategory	Arvelle Therapeutics International GmbH Activities
<b>Donations and Grants</b>	n/a	<p>Funds, assets or services freely given to HCOs for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return.</p> <p><u>Examples:</u></p> <ul style="list-style-type: none"> <li>• Donations and grants</li> <li>• Independent investigator trials IIT (no-profit studies)</li> <li>• Scholarship</li> </ul>

<b>Farmindustria category</b>	<b>Farmindustria subcategory</b>	<b>Arvelle Therapeutics International GmbH Activities</b>
<b>Contribution to Cost of Events</b>	Sponsorship agreements	Sponsorship agreements with HCOs or with Third Parties (PCOs) to manage an Event  <u>Examples:</u> <ul style="list-style-type: none"> <li>• Rental of booths</li> <li>• Advertisement (in paper, electronic or other format)</li> <li>• Sponsoring of speakers/faculty</li> </ul>
	Registration fees	<ul style="list-style-type: none"> <li>• Fees paid for the HCP/HCO to attend events</li> </ul>
	Travel & Accommodation	<ul style="list-style-type: none"> <li>• Travel (e.g., flight, train, taxi, car hires, tolls, mileage reimbursement, parking)</li> <li>• Accommodation</li> </ul>
<b>Fee for services and consultancy</b>	Fees	ToVs resulting from or related to contracts between the Company and HCOs / HCPs under which such HCOs / HCPs provide any type of services to the Company or any other type of funding not covered in the previous categories.  <u>Examples:</u> <ul style="list-style-type: none"> <li>• Speaker fees</li> <li>• Post-marketing surveillance studies</li> <li>• Retrospective Non Interventional Studies</li> <li>• Development of education materials</li> <li>• General consulting / advising</li> </ul>
	Related expenses	ToVs relating to expenses agreed in the written agreement for consultancy / professional service, including: <ul style="list-style-type: none"> <li>• Travel (e.g. flight, train, taxi, car hires, tolls, mileage reimbursement, parking)</li> <li>• Accommodation</li> </ul>
<b>Research and Development Transfers of Value</b>	n/a	Transfers of Value to HCPs or HCOs 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 Regulation N° 536/201412); or (iii) non-interventional studies that are prospective in nature, including relevant ToVs, e.g. for Investigator meetings.

#### Events: details

Where an HCP/HCO does not receive the benefit due to a “no show” (occurring when a HCP fails to attend a meeting they were supposed to), the associated costs are not reported, such as the cost of cancelling a hotel booking or accommodation.

In case of partial attendance, only the benefits received are disclosed.

In case of cancellation of an Event, possible penalties for annulling a confirmed arrangement or order and cancellation fees are not disclosed.

### 3. Disclosure Methodology

<b>Disclosure Scope</b>	Arvelle Therapeutics International Gmbh documents and discloses Transfers of Value that are related to <b>prescription-only medicines</b> and that are made, directly or indirectly, to or for the benefit of a Recipient. <u>Excluded ToVs:</u> <ul style="list-style-type: none"> <li>• transfers of value that are solely related to over-the-counter (OTC) medicines or medical devices</li> <li>• <b>costs of meals &amp; drinks</b> are excluded. However, where meals and drinks make up an integral and inseparable part of contributions to the cost of events or sponsoring as part of Sponsorship Agreements, they have been included in Contributions to Cost of Events.</li> <li>• <b>items of medical utility for HCPs, informational and educational material and samples</b> are not disclosed</li> <li>• <b>ToVs to Patient Organizations</b> are out of scope for this reporting and disclosed separately on the Angelini Pharma website.</li> </ul>
<b>Date of ToVs</b>	The 2021 report discloses ToVs according to accrual principle.
<b>Multi-year contracts</b>	Where contracts are valid for more than one year, only ToVs made in the reporting period are captured and disclosed
<b>Treatment of Value Added Tax (VAT) and other taxes</b>	All transactions are reported in the net amount excluding the VAT and including the withholding tax (if any).
<b>Currency</b>	The amounts are disclosed in Euro. In the case where ToV have been made in a different currency, the Value is converted in Euro.
<b>Language of disclosure</b>	Disclosure is made in English.
<b>Retention of Records</b>	Relevant records of the disclosure are retained for a minimum of 5 years after the end of the relevant Reporting Period
<b>Cross border activities (ToVs made by other Angelini Pharma legal entities)</b>	Arvelle Therapeutics International Gmbh report includes also ToVs to HCPs whose address of principal practice and to HCOs whose address of registration is Switzerland made by any other Angelini Pharma Affiliate or by any other company/branch of Arvelle Group.

### 4. Data Protection and Consent Management

#### HCPs

To process HCP personal data for the disclosure, it is needed to obtain explicit consent from the healthcare professional to process his/her personal data.

- If the HCP provides consent for disclosure, the sum of all ToVs to that HCP during the reporting period is disclosed under his/her name according to the specific ToV category.
- If the HCP does not provide consent to disclosure, all the ToVs in the reporting period are reported in the “aggregate” section, without stating the details of HCP.

Arvelle Therapeutics International Gmbh requires HCP to provide the consent information once per reporting period.

If the consent of HCP was withdrawn, relevant ToVs have been disclosed on an aggregated basis.

## HCOs

Arvelle Therapeutics International GmbH does not obtain consents from HCOs to the disclosure of the transfers of value made to them because legal entities are not subject to personal data protection under the law and therefore the consent collection is not required.

## 5. Definitions pursuant to Farmindustria Code of Conduct

**HCP – Healthcare Professional:** Any person who carries out their activity in the medical sector, dentistry, public, private or hospital pharmacies, any nurses, Administrators or staff of Local Health Authorities, any technical or administrative personnel of public or private healthcare structures and any other person within the scope of their professional activity can prescribe, dispense, purchase or administer a medicinal speciality and that has their activity mainly in Europe. Intermediary pharmaceutical distributors are however excluded.

**HCO – Healthcare Organization:** Any structure whether it is an association or medical, scientific, healthcare or research organisation, (independently from its legal form) such as Hospitals, Clinics, Foundations, Universities, specialisation and training schools (except for patient associations) that have their legal headquarters or main office or activity in Europe, or through which a Doctor may practice.

**ToV – Transfer of Value:** Economic transfers whether direct or indirect, both in cash or kind, carried out for either promotional aims or for the development and commercialisation of pharmaceuticals for human use subject to medical prescription.

The direct transfers are those carried out directly by the Company for the benefit of the recipient. The indirect transfers are those carried out on behalf of the Company by a third party. When ToV are made through a “Third party”, necessary arrangements have been made with third parties to ensure the obligations are fulfilled (Third parties representing the Company or acting on behalf of the Company, provide the Company with a detailed tracker of the ToV made to HCPs and HCOs).