# CNX Therapeutics Ltd Disclosures of Transfers of Value Methodological Statement 2023

CNX Therapeutics Ltd is a speciality, European pharmaceutical dedicated to the treatment of CNS disorders.

CNX Therapeutics Ltd ("CNX" 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 2021 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.

Transfers of Value paid to patient organisations are disclosed separately on the CNX-therapeutics website.

## **Definitions**

**Events**: includes 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 non-interventional studies) organised or sponsored by or on behalf of a company.

**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 all other employees of a member company

**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 where the Company knows or can identify the HCP/HCO that will benefit from the Transfer of Value.

# **Privacy Laws and Consent to Disclose**

When organising activities involving payment of ToVs to HCPS/ORDMs the Company asks them to confirm their written consent for the data to be publicly disclosed . Only those individuals that give their consent are disclosed as individual HCPS/ORDMs.

No partial disclosures will be made: HCPs and ORDMs can only consent to all and not some of their ToVs being disclosed by CNX therapeutics to the ABPI on an individually identifiable basis.

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

The requirement for written consent for disclosure does not apply to Healthcare Organisations

The Company will retain evidence of consent for 5 years

## **Recording and Collation of Data**

All events/projects which include potential ToV payments require a contract and are pre-approved during the approval processes undertaken during the planning of the event or project.

Generally, all data related to payments and Transfers of Value is captured and reported on an "accruals basis" where CNX has directly or indirectly made the payment or made the Transfer of Value.

The Transfer of Value will be recognised based on the payment date.

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.
- ii. 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. CNX 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.

All annual ToV spends are collated manually on a centralised spreadsheet for preparation of the disclosure to the Disclosure UK.

All payments made in a single year to one HCP/ORDM for multiple events or activities within the same category are collated as one figure under the relevant ToV category. E.g. if an HCP has been contracted to speak at two meetings during the year the fee for service will be recorded as one figure under fee for services.

#### **Disclosure**

ToV disclosure is made on the ABPI disclosure template and submitted to the Disclosure UK database in line with the requirements of the ABPI Code 2021

Individual disclosure is listed under ToV category and by HCP/ORDM name

CNX does not allow for any "partial disclosure": HCPs and ORDMs can only consent to all not some of their ToVs being disclosed by CNX to the ABPI on an individually identifiable basis

When an HCP/ORDM has declined individual disclosure, amounts are listed in the aggregated column

HCO disclosure is listed by address and ToV category

## **Validation of Data**

CNX has made 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.

## **Types of Transfers of Value**

**Donations and grants:** collectively, mean providing 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 the pharmaceutical company in return. Donations and grants to individuals are prohibited.

In general donations are physical items, services or benefits in-kind which may be offered or requested. Grants are the provision of funds. *ABPI Code of Practice 2021* 

## 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. Examples of activities sponsored by CNX in this way include; support for a speaker, rental of stand space.

## **Registration Fees for Events**

CNX Therapeutics supports the continuing medical education of HCPs/ORDMs by providing occasional payment of registration fees for medical/scientific events organised or by a third party.

## **Travel and Accommodation for Events**

This subcategory relates to support in the form of payment of travel and accommodation when CNX Therapeutics supports the attendance of HCPs at medical/scientific events organised by third parties. Examples include airfares, train tickets, taxis, tolls, parking fees and hotel accommodation.

In certain circumstances CNX will reimburse expenses to attend CNX organised in person educational meetings and these are disclosed as such.

#### Fees for contracted services

Fees agreed in a formal contract paid to HCPs and ORDMs, or to their employees on their behalf for services rendered where there is legitimate business need. Examples include chairing and speaking at meetings, participation in advisory boards, training services, medical writing.

The 'Fee for service and contracted services' category will include transfers of value relating to Market Research if the identity of the HCP is known by CNX.

## Related Expenses agreed in the fees for service contract

Expenses paid to HCPs and ORDMs, or to their employees on their behalf in association with the provision of a contracted service as described above.

## **Collaborative Working**

**Collaborative Working:** refers to 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. CNX has not engaged in collaborative working during 2021. *ABPI Code of Practice 2021* 

## **Other Considerations**

Payments are presented in GBP

## Non-monetary transfers of value:

The company uses solely monetary transfers of value: cash or cash equivalent.

#### **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.

#### Tax and VAT considerations

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

# **Currency Exchange**

For payments made for non-UK invoices the currency exchange rate to GBP on the first day of the month of payment is used.

#### Multi-year contracts

Where contracts are valid for more than one year, each individual TOV is captured and disclosed in the reportable annual disclosure period.

## **Private Companies**

Where an HCP/ ORDM runs a private company (where he/she is the only employee of the corporation), CNX discloses the transfer of value to the individual HCP/ORDM subject to consent being in place. Where consent is

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not given for individual HCP disclosure the TOV is disclosed against the HCO.

# **Partial Attendance and Cancellation of Events**

Where an HCP/HCO does not receive the benefit/payment due to a no show or a cancellation of event, 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/payments actually received are reported.

Where CNX has to pay cancellation fees to HCP/HCOs as per service contracts, due to cancellation of events, these payments are reported.

If an HCP carries out work under a contract for a service that is subsequently cancelled, only the hours spent on the work are paid for and disclosed accordingly.