

# Methodological note

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Concordia International Rx (UK) Limited **rebranded to Advanz Pharma effective 3<sup>rd</sup> December 2018** is committed to ensuring transparency of relationships with healthcare professionals (HCPs) and healthcare organisations (HCOs) by operating within the Association of British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry and the Irish Pharmaceutical Healthcare Association (IPHA) Code of Marketing Practice for the Irish Pharmaceutical Industry which are both in alignment with the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code on Disclosure on Transfers of Value.

Transfers of Value (ToV) i.e. payments or benefits received by HCPs and HCOs during the 2018 calendar year will be disclosed on a central platform managed by the ABPI and made public on 29<sup>th</sup> June 2019.

The principles applied in this methodological note are relevant to the UK and all other European countries which follow the EFPIA Code of Practice.

## Definitions

### Healthcare Professionals (HCPs)

As defined in the ABPI Code of Practice 2019 under Clauses 1.4 and 1.5. In addition, Concordia International Rx (UK) Limited regards all employees of the National Health Service (NHS) or any private Health Care Provider as HCPs, retired HCPs and academic staff who provide clinical services and support to fall within scope. Note that HCPs have the right to opt out from disclosure of their ToVs at an individual level.

### Healthcare organisations (HCOs)

As defined in the ABPI Code of Practice 2019 under Clause 1.9. As such Concordia International Rx (UK) Limited regards General Practitioners (GP) medical practices and Clinical Commissioning Groups (CCGs) to be in scope.

### Research and Development

As defined in the ABPI Code of Practice 2019 under Clause 23.2 (SI). All payments to healthcare professionals and healthcare organisations related to research and development are disclosed as aggregate figures in accordance with the ABPI and IPHA Codes of Practice.

## Disclosure categories

In 2018 Concordia International Rx (UK) Limited has disclosed the following financial payments:

1. Transfers of value to named individual healthcare professionals (HCPs) who have given their consent to disclose for:
  - i. receipt of support for attendance at third party led educational meetings.
  - ii. fees for providing consultancy services and expenses relating to the consultancy services.

Where consent has not been obtained or where the individual HCP has not consented Concordia International Rx (UK) Limited has declared the total spend as an aggregate figure for the total non-consenting HCPs as a separate line entry within the relevant disclosure category.

Note: HCPs have the right to opt out of individual disclosure.

2. Transfers of value to healthcare organisations (HCOs)
  - i. For payments made to medical associations, healthcare organisations, etc in relation to meetings. This includes direct funding such as sponsorship fees and fees paid for an exhibition stand, and indirect support such as providing a logistics agency or subsidising the cost of registration fees.
  - ii. Fees for service paid to institutions, organisations or associations for services or any type of funding by companies not otherwise covered by the relevant codes.
3. Transfers of value under Research and Development
  - i. Clinical trials, non-clinical trials and non-interventional studies.
  - ii. Market Research.

## ToV Transaction Principles

### VAT

For all ToVs VAT is included.

### Transaction date

Concordia International Rx (UK) Limited will disclose a transfer for value when internal approval has been provided for a project/activity and the funds have been allocated. This may mean that some projects approved in 2018 will be disclosed as part of 2018 annual reporting period even though the payment may not occur until 2019.

### **Multi-year projects**

Where projects run for several years Concordia International Rx (UK) Limited will declare the amount paid relevant to the year in which each part of the payment was made. Thus a project which spans 4 calendar years and includes several individual transfers of value during that time will have four associated disclosures; one for each calendar year showing the value of the transfer made in that specific calendar year.

### **Cross border payments**

All disclosures are made in the country in which the HCP or HCO practice is located. Payments made to UK-based HCP or organisations by Concordia International Rx (UK) Limited's overseas operations are disclosed within the UK.

### **Co-marketing projects**

Where Concordia International Rx (UK) Limited jointly markets a product with another pharmaceutical company, Concordia International Rx (UK) Limited will only declare those payments made directly from Concordia International Rx (UK) Limited bank accounts and listed in the company records as part of its normal business operations. Transfers of value made by its co-marketing partners will be disclosed separately by those organisations.

## **HCP Payments**

### **Data Privacy**

In accordance with Data Protection Act 2018 and General Data Protection Regulation (GDPR), Concordia International Rx (UK) Limited has obtained and retained records of consent from HCPs on an individual activity basis prior to disclosing personal data such as individual transfers of value. Concordia International Rx (UK) Limited has made every effort to secure the necessary permissions. Where consent has not been obtained or where HCPs have not consented, Concordia International Rx (UK) Limited has declared the total spend as an aggregate figure given on a separate line entry within the relevant disclosure category and the % of non-consenting HCPs given as a percentage of the total HCPs receiving a ToV.

### **Market Research**

Where the identity of an HCP participating in a market research project is known to Concordia International Rx (UK) Limited a ToV disclosure will be made at the individual HCP level.

### **Fee payment to private companies**

Where an HCP invoices through their private company for the purposes of their private income, any payments to that company will be regarded for disclosure purposes as a payment to the HCP directly. Similarly for organisations where the majority of employees or contracted suppliers are comprised of HCPs, the full value of payments made to such organisations associated with the services of a named or identifiable individual will be regarded as if it was a direct payment to the HCP.

### **Fee payments to charities**

HCPs who have worked with Concordia International Rx (UK) Limited may ask for their fee to be paid to charity. Concordia International Rx (UK) Limited does not encourage this type of fee payment and all

payments are normally made directly to the HCP; where payment to a charity may occur the disclosure is still made against the individual HCP.

### **Payments to third party organisations for services provided by individual HCPs**

In some cases Concordia International Rx (UK) Limited contracts with HCPs through a third party agency. In such cases, Concordia International Rx (UK) Limited is responsible for ensuring that the HCP completes and signs the agreement of service and consent form contained in the 'Concordia International Rx (UK) Limited's Consultant pack'. Concordia International Rx (UK) Limited will disclose any payments made to the individual HCP by the service agency as if the payment had been made directly by Concordia International Rx (UK) Limited to that HCP.

### **Medical Education Grants**

Concordia International Rx (UK) Limited has been occasionally approached by independent companies to provide funding in relation to medical education projects. Concordia International Rx (UK) Limited's funding policies in these circumstances require that Concordia International Rx (UK) Limited has no influence over the details of the project. As Concordia International Rx (UK) Limited would not influence or select HCPs involved in such projects, Concordia International Rx (UK) Limited would disclose such payments under an HCO category where such definition is met by the independent company.

### **Contributions to meetings**

Concordia International Rx (UK) Limited will disclose all payments made to medical associations, healthcare organisations, etc in relation to meetings. This includes direct funding such as sponsorship fees and fees paid for an exhibition stand, and indirect support such as providing a logistics agency or subsidising the cost of registration fees.

### **Sponsorship for HCPs to attend medical meetings**

Costs declared include registration fees, travel and accommodation. Costs related to subsistence (food) are not declared but the meal costs are regulated by strict industry guidelines.

### **Grants to HCOs for support to attend medical meetings**

Where Concordia International Rx (UK) Limited is requested by an HCO to provide a financial grant to assist its employees to attend third party medical meetings, where possible the payment will be disclosed against a named individual HCP. Where Concordia International Rx (UK) Limited is not aware of the identity of recipient HCPs, the grant is declared against the named healthcare organisation.

Note: The cost of any sponsorship related directly to food is outside the scope of disclosure.

All costs associated with meetings run solely by Concordia International Rx (UK) Limited are outside the scope of disclosure except for fees paid to individual HCPs providing services as speakers, etc.

## **Patient Organisations**

No disclosures for this category have been made in 2018.

All transfers of value to UK-based patient organisations are disclosed directly on Advanz Pharma's Website (<https://www.advanzpharma.com/ethics-transparency>).

## **OTC and Medical Devices**

There are no disclosures related to OTC medicines and Medical Devices.