

# **UK/IRELAND ELECTRONIC CERTIFICATION CERTIFICATE**

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Job Name:	Methodological Note UK & Ireland 2020 FINAL
Job Bag Classification:	Material
Product:	Non-Promotional
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Method of Dissemination:	Other (give details below)
Target Audience:	Reviewers

#### **Declaration and Signatures:**

#### **Originator/Marketing**

To the best of my knowledge, this item complies with the ABPI and/or IPHA Codes of Practice, and if related to a Kyowa Kirin product, is a fair, truthful and balanced representation of the product.

#### **Final Signatories- Certification and Release**

We here certify that this material, or if it is a meeting the meeting arrangements, has/have been examined in its final form and that in our belief it is in accordance with the requirements of the Kyowa Kirin product, is not inconsistent with the marketing authorization and the summary of product characteristics, and is a fair and truthful presentation of the facts about the product.

Document Approvals			
Medical Signatory	Robert Chipperfield robert.chipperfield@kyowakirin.com Medical Signatory - I certify that the above statement is true		
Commercial Signatory	Mrs Nicol Harrow nharrow@kyowakirin.com Commercial Signatory - I certify that the above statement is true		



## Transparency Reporting at Kyowa Kirin Limited Methodological Notes for Transfers of Value for 2020

### 1. Introduction

Kyowa Kirin Limited (KKL) is committed to supporting healthcare and the development of patient care across the UK and Ireland. As such, we are pleased to offer support to the organisations and practitioners who are central to making this happen. The support of Healthcare Organisations (HCOs) or Healthcare Practitioners (HCPs) through the provision of funds or services is essential to this. In accordance with The Association of the British Pharmaceutical Industries (ABPI) Code of Practice 2019 and The Irish Pharmaceutical Healthcare Association (IPHA) Code of Practice V8.4 publishes details about transfers of value to these individuals and organisations annually and are the reference documents for disclosure of Transfers of Value made in 2020.

Each Kyowa Kirin affiliate in Europe is accountable for capturing and validating data in their nation and we make one disclosure per market. This disclosure covers transfers of value to HCPs and HCOs which are registered in the UK and Ireland.

### 2. Scope of disclosure

This disclosure includes the following transfers of value:

EFPIA Category	EFPIA sub-category	Example activities (not exhaustive)
Donations and grants	N/A	<ul><li>Donations to HCOs</li><li>Educational grants</li></ul>
Contribution to cost of events	Sponsorship agreements	<ul> <li>Sponsorship of congresses organised by HCOs or third parties on their behalf</li> </ul>
	Registration fees	<ul> <li>Funding of HCPs to attend congresses</li> </ul>
	Travel and accommodation	<ul> <li>HCP's travel and accommodation costs for attending congresses</li> </ul>



Fees for service	Fees	<ul> <li>Fees for:</li> <li>Chairing or attending Advisory Boards</li> <li>Speaking engagements</li> <li>Medical writing</li> </ul>
	Related expenses	Travel and accommodation expenses relating to the activities above.
Research and Development	N/A	<ul> <li>Activities relating to:</li> <li>planning or conduct of clinical studies</li> <li>clinical trials</li> <li>non-interventional studies that are prospective in nature</li> <li>clinical investigator meetings</li> </ul>

If activities relate to retrospective non-interventional studies then they are included in Fees for Service, rather than Research and Development.

This disclosure (2020) excludes the following transfers of value:

- Hospitality cost (e.g. meals and drinks) unless these are an integral and inseparable part of contributions to the cost of events
- Informational and educational materials and items of medical utility, in line with article 9 of the EFPIA HCP/HCO Disclosure Code
- Logistical costs related to KKI-organised meetings (e.g. room hire)

As the ABPI and IPHA Codes of Practice only relates to transfers of value to HCPs and HCOs, this disclosure does not include:

- Donations to non-HCOs
- Support provided to Patient Organisations. This is disclosed in a separate report.



### 3. Date of Transfers of Value

The date of the transfers of value included in this disclosure is based on date of payment (where the transfer of value is a payment).

If the transfer of value is a benefit in kind, it is based on the date of payment

#### 4. Direct and Indirect Transfers of Value

For direct transfers of value, the recipient is considered to be the person or entity holding the bank account receiving the money.

Kyowa Kirin Limited also provides indirect transfers of value.

In the case of payments that are made through Clinical Research Organisations, these are included under Research and Development and reported in the aggregate

Where a third party has been appointed by an HCO to manage an event, and where the HCO benefits from the transfer of value, these transfers of value are disclosed against the HCO.

Where third parties are appointed by KKI to make travel and accommodation arrangements for HCPs, the transfers of value are reported against the HCP who received the benefit.

#### 5. Cross-border activities

Kyowa Kirin International (KKI) makes best efforts to capture and report all transfers of value to HCPs and HCOs with primary practice in a country with EFPIA Disclosure Code or other transparency reporting requirements. The country of disclosure is based on the HCP's principal practice or the HCO's country of registration.

The methodology for capturing and reporting spend may vary across affiliates within Kyowa Kirin International plc.



#### 6. Consent

In the UK and Ireland HCOs are reported with the need for consent.

HCP's consent is collected at the time of contracting. If consent is not provided, the transfer of value that they have received is included in the aggregate amount. If no response is received a "no" response is assumed, and the data is also reported in the aggregate.

### 7. Disclosure

Our report of transfers of value in 2020 is published on <u>https://international.kyowa-kirin.com/uk/transparency/</u> in English.

The currency used for disclosure is in Sterling for ToVs disclosed relating to the UK and Euro for Ireland.

VAT is included

Any questions regarding this disclosure should be directed to <u>kki compliance northerncluster@kyowakirin.com</u>