Transparency Reporting at Kyowa Kirin
Methodological Note for 2024

1. Introduction

Kyowa Kirin is committed to supporting healthcare and the development of patient care across the Nordics (Denmark, Sweden, Finland, Norway and Iceland) and the Baltics (Estonia, Latvia and Lithuania). We are pleased to do this through providing funds to Healthcare Organisations (HCOs), Patient Organisations (POs) or Healthcare Professionals (HCPs) and through engaging them for services that contribute to the improvement of patient care. In accordance with the EFPIA Code of Practice, local country codes and other relevant law and regulation Kyowa Kirin discloses details about transfers of value to these HCOs, POs and HCPs annually.

Each Kyowa Kirin affiliate in Europe is accountable for capturing and validating data in their country and for ensuring disclosure and reporting for their market.

This disclosure covers transfers of value between 1st January 2024 to 31st December 2024 to HCOs, POs and HCPs registered in the Nordic and Baltic countries.

In Denmark the transparency requirements on HCPs' affiliation with pharmaceutical companies in the EFPIA Code of Practice are implemented within the framework of article 23.02 of the EFPIA Code of Practice. Accordingly, the Kyowa Kirin entities covered by the Danish legislation comply with the requirements laid down in Danish law, including the Medicines Act, Pharmacy Act, Danish Health Act and the associated Executive Orders. This legislation requires both the HCPs and the relevant entities to report any affiliations to the Danish Medicines Agency who publishes all affiliations on their website: https://laegemiddelstyrelsen.dk/da/godkendelse/sundhedspersoners-tilknytning-til-virksomheder/lister-over-tilknytning-til-virksomheder/apotekere,-laeger,-sygeplejersker-og-tandlaeger/liste-over-personer-der-modtager-oekonomisk-stoette-eller-har-tilknytning-til-virksomheder/. Disclosure of affiliations with Danish HCPs is therefore not covered in this note.

In Latvia, under the Cabinet Regulation No. 378 Procedures for Advertising Medicinal Products and Procedures by Which a Medicinal Product Manufacturer is Entitled to Give Free Samples of Medicinal Products to Physicians, the pharmaceutical companies (marketing authorization holders or their representatives) are obliged to report affiliations with HCP's and HCO's to the Latvian Health Inspectorate (**LHI**) until 30 May of each year. LHI publishes all affiliations on their website: https://www.vi.gov.lv/lv/pazinojums-par-biedribam-nodibinajumiem-un-arstniecibas-iestadem-sniegto-materialo-vai-cita-veida-atbalstu-2. Under the Code of Good Practice and Ethics (local implementing code of the EFPIA Code of Practice), disclosures can also be made on the relevant Member Company's website. However, as stated above, reporting to LHI is mandatory. The central platform for reporting in Latvia is managed by the LHI. The amount of information to be reported to the LHI is identical as required under the Annex A of Code of Good Practice and Ethics (available here: https://siffa.lv/wp-content/uploads/2022/12/KODEKSS_updated-on-01012023_final.docx) and as described below.

In Lithuania, the transparency requirements on HCPs', HCO's and POs affiliation with pharmaceutical companies are established in the Law on Pharmacy (Article 51-1) and / or in the Code of Ethics for Pharmaceutical Marketing, adopted by the Association of the Manufacturers of Medicinal Products and by the Innovative Pharmaceutical Industry Association (**Lithuanian Code of Ethics**) (Articles 22, 23 and 24). Under the Article 22.01 of the Lithuanian Code of Ethics, the Kyowa Kirin entities covered by the Lithuanian legislation must comply with the requirements laid down in Law on Pharmacy. These legislations require pharmaceutical companies (marketing authorization holders or their representatives) to report affiliations with HCPs and HCOs to the State Medicines Control Agency (and State Tax Inspectorate, if affiliation is provided as a donation). State Medicines Control Agency publishes such information on their website for two years as of the moment the publication was made:

https://vvkt.lrv.lt/lt/veiklos-sritys/vaistu-reklamos-kontrole/perleistos-vertes/.
Disclosures about aggregated transfer of values for Research and development, as well as transfer of values to POs are only required to be made under the Lithuanian Code of Ethics.

The following covers methodology for the remaining Nordic and Baltic countries where the EFPIA Code of Practice is applicable and transposed by local codes and regulations.

No transfer of values is reportable for Iceland for the disclosure cycle 2024.

2. Scope of disclosure

This disclosure includes the following transfers of value to HCOs and HCPs:

EFPIA Category	EFPIA sub-category	Example activities (not exhaustive)
Donations and grants	N/A	• Donations to HCOs • Educational grants • Investigation Sponsored Studies
Contribution to cost of events	Sponsorship agreements	• Sponsorship of events organised by HCOs or third parties on their behalf
	Registration fees	• Funding of HCPs to attend congresses (with exception of Sweden and Norway as according to local codes and regulations).
	Travel and accommodation	• HCP's travel and accommodation costs for attending congresses (with exception of Sweden and Norway as according to local codes and regulations).
Fees for service	Fees	Fees for: • Chairing or attending Advisory Boards • Speaking engagements • Medical writing • Consultancy
	Related expenses	Travel and accommodation expenses relating to the activities above.
Research and Development	N/A	Activities relating to: • planning or conduct of clinical studies • clinical trials • non-interventional studies that are prospective in nature

		• clinical investigator meetings

If activities relate to retrospective non-interventional studies, then they are included in Fees for Service, rather than Research and Development.
In Lithuania, information on Transfers of Value relating to non-interventional studies that are not within the definition of Research and Development Transfers of Value shall be reported on an individually named basis in accordance with the provisions of the Law on Pharmacy.

This disclosure excludes the following transfers of value :

- Transfer of values that are solely related to over-the-counter medicines (with exception of Lithuania).
- Informational and educational materials and items of Medical Utility governed by Article 17 in the EFPIA Code of Practice.
- Meals governed by Article 10 in the EFPIA Code.
- Medical Samples governed by Article 19 in the EFPIA Code of Practice.
- or transfer of values that are part of ordinary course purchases and sales of medicinal products by and between a Member Company and a HCP (such as a pharmacist) or a HCO do not fall within the scope of the disclosure obligation described above in “General Obligation”.
- Logistical costs related to meetings organised by Kyowa Kirin International (e.g. room hire).

The exemptions apply insofar different rules applied under local codes.

Some HCPs continue to provide advice to the healthcare community after they have retired. Generally KKI include such HCPs in the applicable regulation´s definition of an HCP, however this depends on their role and ability to prescribe and influence.

Furthermore, Kyowa Kirin in the Nordics and Baltics continually disclose a list of POs that Kyowa Kirin has provided support or worked with on a consultancy basis. The disclosure takes place on the websites mentioned in section 7 below within the timelines required in each country by the local codes. Each list will include the information in Article 24 as the minimum of information subject to further local regulation in the Nordics and Baltics. Please see examples of the categories of transfer of values below:

EFPIA Category	Example activities (not exhaustive)
Financial support	• Donations to POs • Educational grants to POs • Sponsorships of events organised by a PO • Funding to attend conferences and event.
Non-financial support	• In-kind donations (e.g. colleague time, educational materials, books, disease awareness, scientific exchange, education, training)

Contracted services and related expenses	Fees for: • Chairing and/or attending Advisory Boards or expert meetings • Speaking engagements • Consultancy arrangements related to patient recruitment

When required locally, Kyowa Kirin - continually or annually - forward a list to the local industry bodies covering a description of interactions with POs in the respective country.

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 the recipient received the benefit.

Some engagements last for more than a year (multi-year contracts) and entails that payments are made as the activity in question progresses upon receipt of corresponding invoices. The Transfers of Value are recorded in the year they are provided and disclosed accordingly.

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 AB 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

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

6. Consent

In the Nordic and Baltic countries HCOs and POs are reported without the need for consent as they are legal entities with the exception of single-person companies.

Since the disclosure of all 2022 data, Kyowa Kirin has been relying on legitimate interest or legal obligation as the legal basis for disclosure purposes and any transfers of value made to HCPs will be publicly disclosed individually on a named basis for the Nordic countries and Lithuania. For any explicit request to opt out, the transfer of value is included in the aggregate amount in the report. Opt out is

not allowed in Lithuania, as the requirement to publish personal data of HCPs related to transferred values is established by the law.

For 2024 consent is collected for Estonia. If no response is received a “no” response is assumed, and the data is also reported in the aggregate.

7. Disclosure

Our information of transfers of value in 2024 is published on affiliate pages found here: Kyowa Kirin International – Home (kyowa-kirin.com

For Sweden, the report is published on LIF’s homepage: Sök öppen rapportering av värdeöverföring (lif.se).

For Latvia, reporting must be done by filling-in the report template available here: https://www.vi.gov.lv/lv/media/5141/download?attachment (Latvian only). The filled template must be signed with a qualified electronic signature and sent to the LHI at vi@vi.gov.lv. Alternatively, filled template can be submitted to LHI using the e-service available here: https://www.latvija.lv/Epakalpojumi/EP113/Apraksts.

The disclosure report for Estonia is published on Kyowa Kirin’s homepage for Sweden (Kyowa Kirin AB).

For Lithuania: (1) Reports on transfer of values to HCPs and HCOs shall be provided by Kyowa Kirin to the State Medicine Control Agency (reports are due by 30 June), except information on values transferred as donation or charity under the Law on Charity and Sponsorship of the Republic of Lithuania. Values transferred as Sponsorship to HCOs shall be provided to the State Medicine Control Agency by the State Tax Inspectorate, based on reports of the recipients of transferred values. This information on values transferred to HCPs and HCOs shall be published on the website of the State Medicines Control Agency (including personal data of HCPs and names of entities / HCOs. (2) The reports on transfer of values to POs and aggregated transfer of values for Research and development shall be disclosed as follows: after publishing the reports on transfers of value by Kyowa Kirin (the reports must be published between 20 and 30 June each year), a notification to the third party specified by Innovative Pharmaceutical Industry Association in Lithuania and Medicinal Product Manufacturers’ Association in Lithuania is required. References to the report on transfer of values shall be published at www.vaistukodeksas.lt by 30th June, inclusively.

The reports are published in English or local language if required by local code.

The currency used for disclosure is local currency. In the case that payments are made in a currency other than local currency, the payment amount is converted to local currency using the daily exchange rate between the two currencies on the day of payment.

All transfers of value include VAT where applicable. Transfers of value to an individual (natural person) are reported as gross amounts.

Data will remain published for 3 years and stored for a minimum of 5 years by Kyowa Kirin. Updates of published data are conducted when necessary to allow for reflection of data updates or consent withdrawal after disclosure submission. In Lithuania the following shall apply data on values transferred to HPSs and HCOs shall be published for 2 years from the first day of its publication on the website of the State Medicines Control Agency; Kyowa Kirin shall keep the data for 3 years from the date of their first publication on the website of the State Medicines Control Agency.

Any questions regarding this disclosure should be directed to infose@kyowakirin.com.