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Methodological Notes to Disclosures of Transfers of Value (ToV) for 2022

ALK-Abelló Ltd

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Summary

As an ethical pharmaceutical company, ALK-Abelló Ltd takes very seriously its responsibilities under the ABPI code of practice and therefore has clear standard operating procedures in place for the approval and processing of all transfers of value to healthcare professionals (HCP), healthcare organisations (HCO), other relevant decision makers (ORDMs), Patient Organisations (PO), including charities and members of the public (MoP)

All requests for support from healthcare professionals and all engagement of healthcare professionals' services undergo a rigorous approval process to ensure the ABPI Code of Practice is adhered to.

All transfers of value and relevant approval documentation are recorded and saved for for 5 years.

Unless organised and paid for by ALK-Abelló Ltd, all contributions towards the costs of events (clause 24) made at the request of healthcare professionals are only paid to hospital, company or charity accounts and not directly to the individual requesting the support. However, for disclosure purposes, all payments are treated as being made directly to the HCP.

Payments for professional services, speaker fees, consultancy etc (clause 24) are made directly to the individual unless requested otherwise.

In the case of multiple payments to one HCP in any one year, different categories of transfer of value are aggregated per HCP to give a total payment to that individual. Itemised details of multiple payments within a category are available on request.

ALK-Abelló Ltd has fulfilled its own tax responsibilities for all transfers of value but is not responsible for the tax obligations of the individuals benefitting from the payments.

VAT

As some of the transfers of value are to individual HCP's and the majority are not registered for VAT, all figures include VAT where applicable.

Cross Border Payments

ALK-Abelló Ltd also markets its products in the Republic of Ireland and as such has included declaration of transfers of value to healthcare professionals in Ireland in the UK disclosure.

Payments to HCP's in Ireland, payments to UK HCPs utilised as speakers outside the UK and all R&D payments were made in Euro and have been converted to GBP at the rate pertaining at the time of payment. Actual amounts paid in Euro are available on file.

Globally, ALK-Abelló uses an internal SharePoint portal for individual country affiliates to record their cross-border interactions with healthcare professionals. This ensures that ALK-Abelló UK can declare transfers of value to UK HCP's from ALK affiliates in other countries. Any cross border ToVs to UK/ROI HCPs/HCOs have been declared in the UK submission. In some case payments were made in Euro. These have been converted GBP at the rate pertaining at the time of payment. Actual amounts made in Euro are available on file.

Fees for Contracted Services and Consultancy

ALK contracts an HCP/HCO for services when there is a genuine and legitimate business need and where the HCP/HCO is qualified and appropriate to provide the services. These services are paid with an honoraria at Fair Market Value and include any receipted travel expenses and subsistence. This are disclosed on ALK's submission.

Research and Development (R&D)

All payments to HCPs and HCOs related to research and development are disclosed as one aggregate figure under R&D Transfer of Value. Costs that are subsidiary to these clinical trial activities are also included in the aggregate amount.

For the purpose of disclosure, research and development transfers of value are transfers of value to a HCP or HCO related to the planning or conduct of:

- non-clinical studies (as defined in the OECD Principles of Good Laboratory Practice)
- clinical trials (as defined in Directive 2001/20/EC)
- non-interventional studies that are prospective in nature and involve the collection of data from, or on behalf of, individual or groups of health professionals specifically for the study.

Multi-Year Contracts and Collaborative Working

ALK-Abelló Ltd has no multi-year contracts in place.

ALK-Abelló Ltd has no joint working agreements in place.

Sponsorship Agreements and Contribution to Cost of Events

ALK may sponsor individual HCO by contributing to the cost of events. To approve such sponsorships ALK must be satisfied that these events are solely arranged for the continuing education of HCPs and ultimately to enhance patient care. The costs associated with these events may include registration fees, travel costs, accommodation and subsistence.

Where ALK have provided an individual HCP with support to attend a bone fide educational course this has been disclosed under this category.

All such payments are disclosed against the HCP even if the payment is made directly to the event or course organiser.

Transfers of Value to Healthcare Organisations (HCOs)

Throughout 2022 ALK-Abelló Ltd made ToVs to HCOs by way of unrestricted grants. These were either for the benefit of patients or for groups of HCPs, such as training, where the individual names of the HCPs are unknown and ALK has no control over the content of such training.

These amounts are disclosed against the relevant HCO.

Non-Monetary Transfers

There were no non-monetary transfers in 2021

Disclosure Consent

Whenever a contract/agreement that results in a Transfer of Value to an HCP or HCO is made a copy of ALK-Abelló Ltd's disclosure agreement is included as part of that contract. This agreement outlines ALK-Abelló Ltd's commitment to total transparency and full disclosure at a named individual HCP and HCO level. However, each HCP/HCO is free to accept or decline disclosure at a named level.

HCPs/HCOs that decline disclosure are included in aggregate.

Donations and Grants to Charities and Patient Organisations

Grants and donations to non-HCOs such as charities and patient organisations are not disclosed on the ABPI platform. Any such payments made by ALK will be disclosed on the ALK UK website at <https://www.alk.net/uk/disclosure>

Request for Payments of Fees to Charities

Occasionally, an HCP who has provided a service to ALK may ask for their fee to be paid to charity or a third party instead. In the interest of total transparency ALK does not allow this practice, and the disclosure is always made against the individual HCP.

Any questions regarding the content of this document should be addressed to ukhudisclosure@alk-abello.com