

Methodological notes on disclosure as referred to in the EFPIA codes / Swiss Pharma Cooperation Code by ALK-Abelló AG, Richtistrasse 11, 8304 Wallisellen

Published on 30th June 2022

Introduction

ALK-Abelló AG, Richtistrasse 11, 8304 Wallisellen ("ALK") is a subsidiary of ALK-Abelló A/S in Denmark. As a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA), ALK-Abelló A/S and its subsidiaries have committed themselves to transparency and undertaken to adhere to the codes published by EFPIA. These include the Disclosure Code and the Patient Organisation Code adopted by EFPIA. As a member of the Swiss EFPIA association scienceindustries, ALK is also bound by the Swiss Pharma Cooperation Code.

ALK publishes benefits granted to healthcare professionals, healthcare organisations and patient organisations as referred to in the EFPIA Disclosure Code, the Patient Organisation Code and the Pharma Cooperation Code.

The 2022 report is based on the data from the 2021 calendar year.

In these methodological notes, ALK describes how the disclosed data have been recorded and aggregated, in accordance with section 3.05 of the EFPIA Disclosure Code and Art. 28 of the Pharma Cooperation Code (code of conduct of the pharmaceutical industry in Switzerland on cooperation with healthcare professional circles and patient organisations):

Definitions:

Healthcare professionals (HCPs) are natural persons who are doctors, dentists and pharmacists – particularly those who work in practices or in hospitals – as well as pharmacists who work in retail businesses and additionally individuals who are entitled to prescribe, supply or administer prescription-only human medicinal products in accordance with the Swiss Law on Therapeutic Products.

Healthcare organisations (HCOs): institutions, organisations, associations or other groups of healthcare professionals who provide healthcare services and consultancy or other services in the healthcare field (e.g. hospitals, clinics, foundations, universities or other educational institutions, scientific societies or professional associations, group practices or networks, but not patient organisations).

Patient organisations are not-for-profit organisations (including organisations to which they are affiliated) that are based or operate in Switzerland, are composed chiefly of patients or such caregivers, and represent the needs of or support patients or such caregivers.

General notes:

Disclosure related to non-prescription medicinal products and medical devices

In addition to prescription-only human medicinal products, ALK also distributes medical devices. As distribution is closely interwoven in the different product categories, it is difficult in practice to differentiate between the product categories when it comes to the provision of benefits-in-kind. For this reason, ALK also discloses benefits-in-kind related to medical devices.

Financial aspects of publication

Benefits-in-kind are disclosed excluding the applicable value added tax (VAT). Benefits-in-kind are published in Swiss francs. Payments from the Danish parent company in Danish krone are converted into Swiss francs at the current exchange rate.

Multi-year contracts

Where the disclosure of benefits-in-kind relates to contracts that run over several years, ALK discloses the benefits-in-kind made under the contract in the year of publication.

Indirect benefits-in-kind

ALK has used its best endeavours also to fully disclose indirect benefits, i.e. payments made by ALK to recipients, e.g. agencies or travel bureaus, through third parties.

Points excluded from the duty of disclosure

In accordance with the EFPIA Disclosure Code and the Pharma Cooperation Code, ALK does not publish the following contributions:

- items of medical utility as well as meals and drinks;
- the free-of-charge supply of medical samples;
- benefits-in-kind related to investigational medicinal products;
- external and internal training courses which ALK invites healthcare professionals to attend, without the healthcare professionals being granted additional benefits-in-kind or coverage of expenses.

Explanations about the individual categories

In-cash or in-kind donations and other in-kind payments and services of value

The following pecuniary benefits fall under this category:

- in-cash donations to healthcare organisations,
- contributions to healthcare organisations for research projects, e.g. investigator-initiated trials.

Benefits-in-kind related to training events/sponsorship agreements with healthcare organisations or with third parties appointed by the latter to run the event:

The following pecuniary benefits fall under this category:

- sponsorship contributions to healthcare organisations (e.g. including for advertising space),
- booth rentals,
- satellite symposia,

- sponsorship of speakers, provided that these are not known by name and are remunerated directly.

Benefits-in-kind related to training events/conference and participation fees to healthcare professionals/healthcare organisations:

The following pecuniary benefits fall under this category:

- fees for conference attendance,
- fees for training event attendance.

Benefits-in-kind related to training events/travel expenses to healthcare professionals/healthcare organisations:

The following pecuniary benefits fall under this category:

- Economy Class flight costs, Business Class flight costs for intercontinental flights,
- 1st class train tickets,
- car journeys at tax-deductible rates,
- parking fees,
- taxi costs,
- necessary overnight stays in business hotels for the duration of the event.

Fees for services and consultancy to healthcare professionals/healthcare organisations:

The following pecuniary benefits fall under this category:

- lectures,
- training courses,
- participation on advisory boards, and
- miscellaneous consultancy services.

Reimbursement of expenditure:

The following pecuniary benefits fall under this category:

- Economy Class flight costs, Business Class flight costs for intercontinental flights,
- 1st class train tickets,
- car journeys at tax-deductible rates,
- parking fees,
- taxi costs,
- necessary overnight stays in business hotels for the duration of the event.

Contributions to patient organisations

- ALK will disclose contributions to patient organisations. In so doing, ALK will describe the contribution and/or the contractual collaboration, e.g. sponsorship agreement, in such a manner that the object of the contribution/contractual collaboration is transparent. Disclosure will be governed by secrecy obligations.

Data protection law aspects

ALK takes compliance with data protection law requirements very seriously and will use its best endeavours to comply with Swiss data protection laws.

1. "**Personal data**" is information that reveals a connection to a natural or legal person. In compliance with the EFPIA Disclosure Code, the following personal data will be collected, stored and processed, as well as potentially published, by ALK:

- Name, practice or business address of the healthcare professional, healthcare organisation or patient organisation,
- The specific value of benefits-in-kind received – directly or indirectly – by healthcare professionals, healthcare organisations and patient organisations from ALK ("benefits-in-kind"). In particular, this includes the following benefits:
 - service and consultancy fees, including travel expenses and overnight costs as well as reimbursement of miscellaneous expenditure,
 - pecuniary benefits related to training events, including conference/participation fees,
 - travel expenses and overnight costs, reimbursement of miscellaneous expenditure, as well as sponsorship,
 - donations and miscellaneous unilateral pecuniary benefits,
 - benefits for research and development, in particular for studies, clinical trials and non-interventional studies.

2. ALK uses personal data for the following **purposes**:

- Publication: Personal data will be published on a publicly accessible website of ALK-Abelló AG in fulfilment of the requirements of the Pharma Cooperation Code.

Publication takes place in the form of a list that states the recipient and further personal data referred to in point No. 1 and reveals what payments and/or benefits-in-kind, in what amount, of what worth, and for what purpose, were received by healthcare professionals, healthcare organisations and patient organisations from ALK in the relevant reporting period. The reporting period is the respective calendar year.

Contributions in the "Research and Development" field are published in an aggregated form for a number of recipients – without individuals being named.

The details are published once a year, at the latest on 30 June of a given year for the relevant preceding calendar year. Publication takes place for a period of 3 years from the time of first publication.

- Storage: Notwithstanding publication, ALK will store personal data for a period of 3 years after the end of the relevant reporting period. This does not affect legal notification, reporting and storage requirements.
- Processing/transmission: Personal data may be transmitted to companies in the ALK group based in the European Union, where the level of data protection required by the EU General Data Protection Regulation (GDPR) also applies. The personal data will be processed there for publication on the Swiss website of ALK.

3. Data subjects' rights: The individuals whose personal data are affected are at all times entitled to request access to the personal data concerning them stored by ALK, the personal data published, as well as the rectification, erasure and blocking of inaccurate personal data in accordance with the legal requirements.

Data subjects may contact the following address regarding data protection matters:

infoch@alk.net

or

Kanzlei Bech-Bruun

Langelinie Allé 35

2100 Copenhagen

Denmark

Telephone: + 45 72 27 30 02

Email: dpo.alk@bechbruun.com

Secure email via: <https://dpo.bechbruun.com/alk>

Data subjects have the right, at any time, to receive the personal data concerning them in a structured, commonly used and machine-readable format and to transfer them to third parties.

They have the right to lodge a complaint with the competent supervisory authorities at any time.

4. Questions: If data subjects have questions in connection with the processing of their personal data, they may contact the above-named data protection officer at any time.

5. Right of withdrawal: Consent is voluntary. Data subjects can withdraw their consent regarding ALK at any time without detriment to themselves. In this case, data already published will be erased from the above-named website. The lawfulness of the processing of personal data up to withdrawal remains unaffected by withdrawal.

6. Processing of data if consent to publication has not been granted:

- Aggregated publication: If data subjects do not consent to the publication of their personal data, ALK-Abelló AG will process the personal data for the purpose of contract execution and/or fulfilment as well as to permit aggregated publication. Under the terms of the Pharma Cooperation Code, ALK is obliged to publish, in aggregated form, contributions to individuals who have not given consent. In this case, the sums received by data subjects from ALK will be published in aggregated form with other recipients' sums without them being named on an individual basis.

There is a justified interest on the part of ALK to process the personal data in order to be able to carry out aggregated publication. The company is obliged to do this under the

Pharma Cooperation Code.

The individuals whose personal data have been collected, stored and processed will have been informed that the granting of their consent to publication is voluntary, that this is not a requirement for entering into an agreement, and that it will not be to the detriment of the data subjects if they do not grant this consent and that they may withdraw consent at any time.

Consent to publication is granted for a 3-year period.

Miscellaneous

ALK undertakes to review these methodological notes at regular intervals, at least once a year, and to update them where appropriate.

For queries about disclosure and about the methodological notes, please contact Bettina Castan, bettina.castan@alk.net.