

Methodology Note

Open reporting of transfers of value BioArctic Norge AS 2024



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Introduction

In 2013, EFPIA (European Federation of Pharmaceutical Industries and Associations) adopted a new ethical code of conduct, which means that value transfers to healthcare professionals (HCPs) and healthcare organisations (HCOs) will be made public.

As a member company of Legemiddelindustrien (LMI) in Norway, BioArctic Norge AS is obliged to report transfers of value (ToV) to Norwegian healthcare professionals and to healthcare organisations as well as transfers of value linked to research and development in Norway.

This methodology note provides information for understanding how relevant transfers of value from BioArctic Norge AS to HCPs and HCOs in 2024 have been collected and reported.

Reporting is done in the EFPIA template in Norwegian.

BioArctic conducts research and development of medicinal products for the treatment of neurodegenerative disorders. No medicinal products have been marketed or provided to the market in 2024.

Definitions

Transfer of value shall mean direct and indirect transfers of value, whether in cash or in kind, to or for the benefit of recipients, which takes place in connection with the development or sale of medicinal products exclusively for human use, irrespective of whether or not the purpose is promotional.

Transfer of value for research and development shall mean transfers of value to recipients related to the planning or conduct of non-clinical studies, clinical studies or non-interventional studies which include the collection of patient data from or on behalf of healthcare personnel.

Healthcare Personnel (HCP) shall mean a person as defined in the Medicines Regulation § 13-7 or in the Health Personnel Act, as well as others who work in a health organization with healthcare or patient treatment. Healthcare personnel such as a physician, dentist, pharmacist, nurse or other persons within the healthcare system, who have the right to prescribe, purchase, distribute, recommend or administer a medical product, may fall within the definition of healthcare personnel.

Healthcare Organisation (HCO) shall mean any legal entity (i) that provides healthcare or patient treatment, such as a healthcare enterprise, medical practice, etc. (ii) that is a research or teaching institution in medical, biological or health-related subjects, such as a university or other learning institution, (iii) through which Healthcare Professionals provide healthcare services, or (iv) that is a Healthcare Professionals Association (non-commercial association of Healthcare Professionals who have a common interest, cause or field of expertise they wish to promote). Companies such as private limited companies, trading companies or sole proprietorships are also considered healthcare organizations.



Transfers of value relevant to BioArctic Norge AS

Transfers of value to HCP and HCO

In 2024, transfers of value were carried out linked to the following activities:

- Service and consultancy; fee and related expenses

Transfers of value to Research and Development

In 2024, no transfers of value were carried out linked to Research and Development activities as defined above.

Collection of transfers of value

Relevant transfers of value in 2024 were collected by continuously tracking service and consultancy agreements. Following year's end a reconciliation was performed against payment of salaries and invoices.

Reporting of transfers of value

Sampling based on payment date

The report includes all transfers of value to individuals and entities that fall under the definition of healthcare professionals (HCPs) or healthcare organisations (HCO), and where payment dates were in 2024 (irrespective of the contract date, contract duration or event date).

Currency

Value transfers are reported in NOK. In cases where the value transfer has been made in another currency, the value transfer is reported in NOK according to the exchange rate that applied at the time of payment.

VAT management

All value transfers are reported excluding VAT.

Fees and expenses

For fees paid as salary, the gross salary amount and no social security contributions are reported. For fees that are invoiced, the invoiced amount is reported excluding VAT. Likewise, expenses in connection with the performance of the assignment are reported excluding VAT.

Legal basis for disclosure

BioArctic Norge AS uses legitimate interest (for more information on the concept of legitimate interest, see Article 6 (1) (f) of the EU General Data Protection Regulation (2016/679, GDPR)) as the disclosure processing basis. In contracting the healthcare professional is not specifically asked to consent to the disclosure of their information.



A healthcare professional is always free to refuse to cooperate if they do not want their information to be published. In addition, the data subject always has the right to object to the processing of his/her data. In this case, the disclosure will not be made in the name of the data subject, but the information will be published in aggregate form so that the individual cannot be identified. The data subject also has the right to object to the processing of his or her data afterwards, in which case the data will be deleted from the public registers without delay.

Transfer of value out of scope for reporting

Transfers of value from another company with a collaboration agreement with BioArctic are reported by that other company and not by BioArctic.

Publication

BioArctic's report for 2024 is published on www.bioarctic.no.

Contact

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