



METHODOLOGY NOTES

TRANSPARENCY DISCLOSURE FOR TRANSFERS OF VALUE (ToV) TO HEALTHCARE PROFESSIONALS (HCP), HEALTHCARE ORGANISATIONS (HCO) AND PATIENT ORGANISATIONS (PO)

Country of Disclosure: Belgium

Year of Disclosure: 2019 for 2018 data

This document is intended to guide the readers in understanding how Norgine derived and calculated the amounts presented in their 2018 disclosure, as each company may approach disclosure in slightly different ways. This document covers the period from 01st January 2018 to 31st December 2018.

1. Introduction to Norgine

Norgine is a European specialist pharmaceutical and medical device company that has been established for over 100 years. Norgine employs over 1,000 people in Europe and Australia.

Norgine provides expertise and ‘know how’ in Europe to develop, manufacture and market products that offer real value to healthcare professionals, payers and patients.

Norgine is headquartered in the Netherlands. Norgine owns a Research & Development site in Hengoed, Wales and two manufacturing sites, one in Hengoed, Wales and one in Dreux, France. For more information, please visit www.norgine.com.

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2. Introduction to Transparency Disclosure and the Purpose of this Document

The European Federation of Pharmaceutical Industries and Associations (EFPIA) Disclosure Code, Medtech Europe and the Belgian Sunshine Act call for greater transparency between the companies and Healthcare Professionals (HCPs), Healthcare Organisations (HCOs) and Patient Organisations (POs). More information can be found at <https://www.efpia.eu/relationships-codes/>, <https://www.medtecheurope.org/interactions-with-the-medical-community/transparency/>, and <https://www.betransparent.be/wp-content/uploads/2017/01/Moniteur-Belge-2016-12-27-Belgisch-Staatsblad.pdf>.

The Belgian Sunshine Act requires that pharmaceutical and medical device companies document and publicly disclose certain transfers of value made directly or indirectly to HCPs, HCOs and Patient Organisations located in Belgium.

Norgine continues to publicly disclose the financial support and/or significant indirect/non-financial support to Patient Organisations on its corporate website (www.norgine.com) as it has done since transparency requirements began in 2012. This is because Norgine believes in interacting with and providing financial support to patient organisations to ensure high quality provision of information for patients so that, in consultation with their healthcare professionals, they can make well-informed choices about their health and treatment and ultimately improve their experience and outcomes.

Since the entry into force of the Sunshine Act in 2017, transparency on transfers of value has become a legal obligation in Belgium. Before, transparency was autoregulated via Pharma.be. It is recorded since 2016 in www.betransparent.be. This website can be used to search the Healthcare Transparency

Register. Betransparent.be offers insight into certain financial relationships between companies and healthcare providers, partnerships of healthcare professionals, institutions which employ healthcare professionals and (since 2017) patient organisations.

Financial relationships imply payments, in money or kind, done by companies to, for example, a physician or other healthcare provider or hospital. You can search Betransparent.be to find out if and for what a physician or institution has received such sponsorship. Betransparent.be has been established by physicians, healthcare providers and –institutions and companies with the aim of being transparent concerning the cooperation between healthcare parties.

Collaborative working between healthcare professionals and commercial life sciences organisations has long been a positive driver for advancements in patient care and progression of innovative medicine. Both parties regularly join together, during early scientific research, clinical trials and medical education in the interests of delivering and advancing high quality patient care. As the primary point of contact with patients, the medical profession can offer invaluable and expert knowledge on patients' behaviour and management of diseases. This plays a big part in informing the pharmaceutical and medical device industry's efforts to improve patient care and treatment options – and is essential in improving health outcomes.

A healthy working relationship between the pharmaceutical and medical device industry and HCPs/HCOs/POs is in the best interest of patients. Disclosure codes protect the integrity of these relationships, and represents a step towards fostering greater transparency and building greater trust between the industry, the medical community and society across Europe.

Norgine believes that relationships and collaborations between healthcare professionals and the pharmaceutical and medical device sector are mutually beneficial and have a profound and positive influence on the quality of patient treatment and the value of future research. Increasingly, experienced HCPs are called upon to inform product development and explain why therapies and innovations are necessary and demonstrate value to patients.

Norgine reviews its business code, compliance policies and procedures regularly and makes changes as appropriate based on both external and internal factors, to ensure its business practices reflect all relevant laws, regulations and industry codes that govern the company's business, while maintaining patient safety at all times.

In Europe, each company providing transfers of value to a HCP, HCO or PO must publish a note summarising the methodologies used for preparing the disclosures and identifying each category of transfer of value.

Norgine will disclose all Transfers of Value to HCPs, HCOs and POs in accordance with the Sunshine Act, the EFPIA Disclosure Code and Medtech Europe.

Betransparent.be was established in 2016 as an initiative of Pharma.be for the purpose of providing insight into financial relationships between healthcare providers and pharmaceutical companies. Betransparent.be manages a central database which can be used by the public to consult data on certain financial relationships between pharmaceutical companies and physicians, healthcare providers, partnerships of healthcare professionals, institutions which employ healthcare professionals and patient organisations. Transparency is of importance in other branches and occupational groups as well. Therefore Betransparent.be has been established independently of Pharma.be.

Betransparent.be processes the data on pharmaceutical and medical device companies and healthcare providers and –institutions including patient organisations. For more information on rules and regulations with regard to transparency, please visit the website www.betransparent.be.

The Rules of Conduct Disclosure Financial Relationships include the obligation to physicians, pharmacists, nurses and physician assistants on the one hand and pharmaceutical and medical device companies on the other to report data on service, consultancy and sponsorship relationships to the register.

Transfers of Value to the Belgian HCOs, HCPs and POs that occurred between 1st January to 31st December 2018 are available on a central platform managed by Betransparent.be and will be made public by end of June 2019; a link to this central platform will also be disclosed on the Norgine corporate website (www.norgine.com).

Norgine develops and commercialise both medicinal products and medical devices across different countries. In line with the Sunshine Act, Norgine reports transfers of value both related to medical devices and to medicinal products in this disclosure.

For non-monetary transfers of value, a perceived equivalent value to the recipient is stated.

3. Definitions

Norgine has kept the EFPIA Code definitions of Healthcare Professionals (HCP), Healthcare Organisations (HCO) and Patient Organisations (PO).

Healthcare professional (HCP): Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product or medical device and whose primary practice, principal professional address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCP includes: (i) any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products or medical devices and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.

For the purposes of disclosure, Norgine regards all employees of the national public health service or any private Healthcare Provider as HCPs regardless of their professional status. In addition, Norgine regards all registered or qualified healthcare professionals as within the scope of disclosure regardless of their national public health service status. Thus retired HCPs fall within scope and academic staff who provide clinical services and support too.

The salary and benefits of members of staff that are solely employed by Norgine as physicians are outside the scope of this disclosure.

Any Norgine employee whose primary occupation is that of a practising HCP are in scope of this disclosure. Transfers of value to that group will therefore be disclosed, including their salary from Norgine.

Healthcare Organisation (HCO): Any legal person (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations within the scope of the EFPIA PO Code) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.

Patient Organisation (PO): Organisation, specifically in charge of patients' representation

Norgine collectively refers to HCP, HCO and POs as healthcare customers.

Transfer of value: a direct or indirect transfer of value, whether in cash, in kind (e.g. provision of administrative support) or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines. A direct transfer of value is one made directly by a company for the benefit of a recipient. An indirect transfer of value is one made on behalf of a company for the benefit of a recipient or through an intermediate and where the company knows or can identify the recipient that will benefit from the transfer of value.

Donations and Grants: Donations and Grants, collectively, means those donations and grants (either in cash or benefits in kind or otherwise) to institutions, organisations or associations that are comprised of healthcare professionals and/or that provide healthcare or conduct research. Grants are provided to fulfil a specific purpose, but for which the specific activities needed to undertake it have not been defined. They are only allowed if: (i) they are made for the purpose of supporting healthcare or research; (ii) they are documented and kept on record by the donor/grantor; and (iii) they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. Donations and grants to individual healthcare professionals are not permitted.

4. Data privacy and consent

Norgine fully supports the concepts of transparency and discloses transfers of value data on a nominative, individual HCP, HCO or PO base. While permission from individual HCPs was obtained prior to disclosing personal data under the self-regulation code, the binding nature of the Sunshine Act causes the absence or refusal of consent of HCPs not to be an obstacle for data collection and publication.

Norgine does not enter into agreement with HCPs, HCOs or POs who refuse to abide by the principles of transparency.

Every time Norgine enters into an agreement with a HCP or HCO for a given interaction (e.g. project work, meeting, event, grant, consultancy fee), the contractual agreement includes the disclosure obligations.

Norgine informs beneficiary HCPs about the purpose of the data collection, the public disclosure for 3 year on public sites, the 10 years retention period of the data and the rights of the HCP (data access, data rectification/erasure, data portability, restriction of processing, right to lodge).

5. Research and Development (R&D)

All payments to HCPs, HCOs and POs 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, HCO or PO 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.

Because Clinical Research Organisations (CRO) are not regarded by Norgine as HCOs, any R&D transfers of value made by the CRO to HCP, HCO or PO are declared as part of the R&D aggregate disclosure.

6. Transactions

Transaction Date versus Service Delivery Date

Norgine handles and declares the transfers of value from the time of payment to the healthcare customer, i.e. the transaction date, rather than when the service, interaction or event actually occurred. This means that there could be some instances where the transfers of value disclosed this year are reported the following year, and also transfers of value related to the year preceding the disclosure made this year.

Transfers of value will always be paid after the engagement has taken place, with the exception of grants (see definition). Grants will be paid before the event actually takes place, or the purchase to what the grant is for.

Management of Multi-Year Contracts

In a similar spirit to the above point, where projects run for several years, Norgine declares the amount paid relevant to the year in which each part of the payment was made. Thus a project which spans 2 calendar years and includes several individual transfers of value during that time will have two associated disclosures (i.e. one for each calendar year showing the value of the transfer made in that specific calendar year).

VAT

Fees and honoraria consultancy exclude VAT and recoverable local taxes.

Expenses related to an event or meeting (travel, accommodation, taxi) may include VAT or local taxes where applicable.

VAT, if included, is the national VAT of the country where the spend is incurred.

Handling of Currency and Exchange Rates

The values in the disclosure template are expressed in local currency, i.e. Euros for the Belgian data, regardless of whether the HCP, HCO or PO got paid in that currency.

Where values had to be converted into Euro from another currency, the exchange rate used was the Norgine Annual Budgetary Conversion Rate at the time of the transaction.

7. Complicated Payment Routes

Payments to Charity and Third Parties

Occasionally, a HCP who has provided a service to Norgine may ask for their fee to be paid to charity or a third party instead. Typically Norgine does not allow this practice, and the disclosure is made against the individual HCP because the contract is between Norgine and the HCP, the HCP provided the service and received the transfer of value. It is up to the HCP to transfer the payment upon receipt to a charity or third party of their choice should they chose to do so, and that further transaction is outside the control of Norgine.

Norgine regularly contracts with advertising agencies and public relations agencies for services related to its business and where a HCP may be contracted to perform a service for Norgine. Norgine discloses any transfers of value made to the individual HCP by the service agency as if the payment had been made directly by Norgine to that HCP.

Payments to HCO/PO for services provided by individual HCP

Occasionally, a HCO/PO may request that any services provided by its HCP employees must be a contracted through the HCO itself and cannot be contracted with the individual HCP. In the case that Norgine is contracting for the services of a named HCP, the transfer of value is disclosed under that named HCP. Any “administration fee” charged by the HCO is disclosed as a fee for service to that HCO. If the HCP does not receive any additional payment for the service (e.g. because they are speaking at a meeting during normal working hours) then the full amount paid by Norgine will be disclosed against the healthcare organisation as a fee for service.

Private companies and associated charities

In the event of a HCP running a private company or partnership or charity for the purpose of their private income, any transfers of value made to that organisation will be regarded for disclosure purposes as a payment to the HCP directly.

8. Medical Education Grants

Grants to Independent Companies

From time to time, independent companies running medical education projects may request a grant from Norgine to sponsor or fund their work. In such case, Norgine has no influence over the detail of the project, and might not know immediately whether or which HCP has been (sub)contracted. Transfers of value are disclosed accordingly against the HCO (or PO).

Grants and Donations

When Norgine is asked to provide a grant or make a donation to a HCO/PO to assist its employees to attend medical or scientific meetings (i.e. that could include the contribution to registration fees, or travel and accommodation), the associated transfers of value will be disclosed accordingly against the HCO/PO, unless the request is associated with named individuals. If the request is associated with a named HCP, the disclosure is made as if the named HCP directly benefitted from the transfer of value. Where Norgine is not aware of the names of the HCPs receiving the support, the grant is declared against the HCO/PO that made the request.

9. Contributions to Meetings

Norgine disclose all payments made to medical associations and HCO/POs in relation to meetings. This includes direct funding such as sponsorship fees or the right to erect an exhibition stand, and indirect support such as providing a logistics agency or subsidising the cost of registration fees, travel and accommodation. Expenses to attend company-arranged meetings are also disclosed, and the detail of all these transfers of value are provided in the relevant line entry.

Costs related to subsistence are outside the scope of the disclosure since the meal costs are regulated by strict industry guidelines. Occasionally, subsistence may have to be included when it is not possible to single out the cost of the food because it is included as part of a general receipt containing other costs that must be disclosed.

Norgine supports the attendance of HCPs at medical and scientific meetings. Where costs are not individually itemised (e.g. the cost of a bus transferring a group of HCPs from an airport to a conference venue), the total cost is split equally between all those receiving the benefit.

10. Cross-Border Payments

Norgine has Affiliates in many countries within and outside the European Union.

Transfers of value made by any Norgine entity is disclosed in the relevant disclosing template in the correct local currency of the practising healthcare customers. All disclosures are made in the country in which the HCP practices or in which the HCO/PO is located.

Transfers of value made to Belgium-based organisations by Norgine's overseas operations are disclosed in Belgium regardless of the source of funding. This means that this disclosure contains all transfers of value that Norgine has made to Belgian HCP, HCO and PO regardless of which Norgine entity has actually made the transfer of value.

The same applies for transfers of value made by the Belgium Affiliate to other non-Belgium HCP, HCO or PO, they do not feature in the Belgium disclosure but in the relevant template(s) of the country(ies) responsible for disclosing those transfers of value instead.

11. Co-Marketing Projects

Where Norgine jointly markets a product with another pharmaceutical company, Norgine declares the transfers of value made directly from its own bank accounts and listed in the company financial books as part of its normal business operations. Transfers of value made by its co-marketing partners are disclosed separately by those organisations. Responsibility regarding transparency disclosure should be clear from the contractual partner agreements.

Any questions regarding the content of this document should be addressed to belgium.info@norgine.com or contact@norgine.com.