



METHODOLOGY NOTES

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

Country of Disclosure: Ireland

Year of Disclosure: 2016 for 2015 data

This document is intended to guide the readers in understanding how Norgine derived and calculated the amounts presented in their 2016 disclosure, as each pharmaceutical company may approach the problems in subtly different ways.

1. Introduction to Norgine

Norgine is a European specialist pharmaceutical company that has been established for over 100 years. In 2015, Norgine's total revenue was EUR 317 million and the company employs over 1,000 people.

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 and its global operations are based in Amsterdam and in Harefield, UK. 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 calls for greater transparency between the pharmaceutical companies and Healthcare Professionals (HCPs) and Healthcare Organisations (HCOs) – cf.

<http://transparency.efpia.eu/uploads/Modules/Documents/efpia-disclosure-code-2014.pdf>.

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.

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 industry's efforts to improve patient care and treatment options – and is essential in improving health outcomes.

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

In line with this Code, Norgine believes that relationships and collaborations between healthcare professionals and the pharmaceutical 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 make 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 or HCO must publish a note summarising the methodologies used by it in preparing the disclosures and identifying each category of transfer of value.

Norgine will disclose all Transfers of Value to HCPs and HCOs in accordance with its commitment to the Code of Practice of the Association of British Pharmaceutical Industry (ABPI) and Irish Pharmaceutical Healthcare Association (IPHA) which are both in alignment with the EFPIA Disclosure Code.

The term '**transfer of value**' means a direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of prescription-only medicinal products exclusive for human use. Direct transfers of value are those made directly by a company for the benefit of a recipient. Indirect transfers of value are those made on behalf of a company for the benefit of a recipient, where the identity of such company is known to, or can be identified by the recipient. For more information please go to <http://www.ipha.ie/alist/publications.aspx?article=f8f9c1e9-344a-468c-b7d2-dc83530513b1> In the Republic of Ireland, the IPHA Code 2015 Edition 8.1 defines the term 'transfer of value' in a similar manner (Annex V). For more information please go to <http://www.ipha.ie/alist/codes-of-practice.aspx>.

Transfers of Value to Irish HCOs and HCPs that occurred between 1st January to 31st December 2015 are available on a central platform managed by the IPHA and will be made public by 1st July 2016; 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. Although there are currently no transparency requirements for medical devices in Europe, Norgine reports transfers of value where there is a possible overlap between the services that a HCP may provide that spans across both class of products, or that could be perceived as influencing the judgement of the contracted HCP. Transfers of value solely related to medical devices are not yet reported in this disclosure.

The same transparency process applies where Norgine has Over the Counter products.

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) and Healthcare Organisations (HCO) and taken the IPHA Code definition for Other Relevant Decision Makers (ORDM).

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 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 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 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 associations within the scope of Annex III of the IPHA Code) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more healthcare professionals provide services. **Other Relevant Decision Makers (ORDM):** includes those who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who are not health professionals (e.g. payors).

Transfers of value made to ORDM are disclosed with HCP transfers of value.

Norgine collectively refers to HCP, HCO, ORDM and Patient Organisations as healthcare customers.

Donations and Grants:

Collectively means those donations and grants (either cash or benefits in kind) within the scope of Clause 15 of the IPHA Code. Any such support provided by a company must be relevant to the practice of medicine or pharmacy and must be given to an institution rather than to an individual healthcare professional and intended solely for use in the institution.- Any such support must not be linked in any way with product promotion. No commitment must be sought or given in relation to the prescribing, supply or use of the company's products. Any such support must be reasonable, modest and in proportion to the scale and scope of the recipient institution and must be likely to appear so to independent third parties..

Norgine fully supports the concepts of transparency and data privacy. Data Privacy law requires that all pharmaceutical companies, and therefore Norgine, obtain permission from individual HCPs prior to disclosing personal data such as individual transfers of value made to them and attributable by name.

Norgine only enters into an agreement with a HCP, ORDM or HCO if they consent to having their data publicly disclosed either in an aggregate or individual manner. Norgine does not enter into agreement with HCPs who refuse to abide by the principles of transparency. HCPs have the right to opt out from individual disclosure and revoke their consent at any time, and Norgine has to abide by their preferences.

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 clearly indicates the type of disclosure agreed (i.e. consented to) by the healthcare stakeholder. Norgine will seek consent to disclose transfers of value made to a HCP or HCO for each transaction or interaction they are contracted for. This means that for the same disclosure year, the same HCP or HCO can opt to have some transfers of value published individually (via individual disclosure) and others aggregated (via aggregate disclosure).

Where permission has not been obtained or where the individual HCP has refused to provide consent on an individual basis, Norgine has declared the total spend as an aggregate figure. In the spirit of transparency, Norgine seeks the consent to disclose all of its transfers of value at an individual level so new consent is sought for each new interaction or project.

In alignment with EFPIA Code, support to Patient Organisation is done at an individual level and without any specific consent sought or provided. Norgine will provide sufficient information about the nature of the payments to inform the readers about the interaction. Information about support to Patient Organisation is published on Norgine corporate website and does not form part of this disclosure – cf. www.norgine.com.

4. Research and Development (R&D)

Research and Development Transfers of Value Transfers of value to healthcare professionals or healthcare organisations related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice⁸); (ii) clinical trials (as defined in Directive 2001/20/EC⁹); or (iii) non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, healthcare professionals specifically for the study. 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. Because Clinical Research Organisations (CRO) are not regarded by Norgine as HCOs, any R&D transfers of value made by the CRO to HCP or HCO are declared as part of the R&D aggregate disclosure

5. 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 in 2016 are reported in 2017, and also transfers of value related to 2015 made in 2016.

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, i.e. 23% in Ireland

Handling of Currency and Exchange Rates

The values in the disclosure template are expressed in local currency, i.e. GBP for the UK data, and Euros for the Irish data.

Where values had to be converted into GBP from another currency, the exchange rate used was the Norgine Annual Budgetary Conversion Rate at the time of the transaction, or for 2015, 1 Euro = 0.8033 GBP equivalent to 1 GBP = 1.2449 Euros

6. 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 for services provided by individual HCP

Occasionally, a HCO 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.

7. 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 whether or which HCP has been contracted. Transfers of value are disclosed accordingly against the HCO.

Grants and Donations

When Norgine is asked to provide a grant or make a donation to a HCO 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, 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 that made the request.

8. Contributions to Meetings

Norgine disclose all payments made to medical associations and HCOs 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.

9. Cross-Border Payments

Norgine has Affiliates in many countries inside 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 is located.

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

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

10. 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 contact@norgine.com or UK-TOV@norgine.com