

Country of Disclosure: Poland

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

1. INTRODUCTION TO NORGINE

Norgine is a European specialist pharmaceutical company that has been established for over 110 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 HCPs, 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. TRANSPARENCY DISCLOSURE AND THE PURPOSE OF THIS DOCUMENT

In Europe, the European Federation of Pharmaceutical Industries and Associations (EFPIA) Disclosure Code calls for greater transparency between the pharmaceutical companies and HCPs and HCOs, meaning that pharmaceutical companies are required to disclose the ToV they make, directly or indirectly, to them.

, For Poland, Norgine Ltd follows the requirements of the EFPIA Code that requires that pharmaceutical companies document and publicly disclose certain ToV made directly or indirectly to HCPs, HCOs and Patient Organisations located in Europe and where transparency requirements exist. More information about the HCP and HCO Code can be found at https://www.efpia.eu/media/24302/3a_efpia-hcp-code-2014.pdf

Norgine develops and commercialises both medicinal products and medical devices across different countries. Norgine reports ToV for medical devices separately to those for medicinal products. In the event of 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, Norgine exercises its best judgement to report the ToV in the most suitable category of product or device. 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 evaluated and stated.

By ToV we mean payments such as donations and grants made to HCOs and in the case of HCPs, fees for services or sponsorship to attend educational events such as medical congresses.

When the disclosures are published they include the name of the HCP or HCO if individual consent was provided, and the total amounts of value received by that individual or organisation in the previous calendar year. The figures are broken down into categories of activity.

For HCOs specifically, there are two categories:

- donations & grants
- contribution to costs related to Events (sponsorship agreements).

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For HCPs and HCOs the categories are:

- contributions to costs related to events (such as registration fees, travel and accommodation for attending medical congresses, etc.)
- fees for services and consultancy (for example, speaker fees, consultancy).

Payments made for R&D non-clinical studies, clinical trials and non-interventional studies prospective in nature are disclosed in aggregate.

Those ToV are disclosed on Norgine corporate website (www.norgine.com).

DEFINITIONS

Norgine has kept the EFPIA Code definitions of HCP and HCO.

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 or where transparency requirements exist. 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 HCPs 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. In addition, payers are also included within this definition.

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. ToV 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 Patient Organisations Code) whose business address, place of incorporation or primary place of operation is in Europe or where transparency requirements exist or (ii) through which one or more HCPs provide services. For the purposes of disclosure, Norgine regards healthcare associations and steering committees made of HCPs as HCOs.

Norgine collectively refers to HCP, HCO and Patient Organisations as Healthcare Customers.

Transfer of Value: a direct or indirect ToV, 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 ToV is one made directly by a company for the benefit of a recipient. An indirect ToV 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 ToV.

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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 HCPs 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 HCPs are not permitted.

4. DATA PRIVACY & CONSENT

Norgine fully supports the concepts of transparency and applicable regulations including data protection laws and obtains permission from individual HCPs and HCOs prior to disclosing personal data such as individual ToV made to them and attributable by name. Where a HCP or HCO does not grant consent, the payments are disclosed in aggregate and instead Norgine publishes the number of HCPs and HCOs that did not give their consent and the total amount paid to them. disclosure and revoke their consent at any time, and Norgine has to abide by their preferences.

In the spirit of transparency, Norgine actively seeks the consent to disclose all of its ToV and new consent is sought for each new interaction or project.

HCPs and HCOs have the right to opt out from individual disclosure and revoke their consent at any time, and Norgine has to abide by their preferences.

Where permission has not been obtained or where the individual HCP or HCO has refused to provide consent on an individual basis, Norgine declares the total spend as an aggregate figure.

5. RESEARCH AND DEVELOPMENT (R&D)

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

For the purpose of disclosure, R&D ToV are ToV 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.

R&D ToV made by Clinical Research Organisations (CRO) on behalf of Norgine to HCPs or HCOs are declared by Norgine as part of the R&D aggregate disclosure, in each relevant country.

6. TRANSACTIONS

Transaction Date versus Service Delivery Date

Norgine handles and declares the ToV from the time of payment to the Healthcare Customer, i.e. the transaction date, rather than when the service, interaction or event

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actually occurred. This means that there could be some instances where the ToV disclosed this year are reported next year, and also ToV related to last year made this year.

ToV 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 ToVs during that time will have two associated disclosures (i.e. one for each calendar year showing the value of the transfer made in the specific calendar year).

VAT

Fees and honoraria consultancy typically 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 Poland.

Handling of Currency and Exchange Rates

The values in the disclosure template are expressed in local currency, i.e. in Polish Zloty for the Polish data, regardless of whether the HCP or HCO was originally paid in that currency.

Where values had to be converted into Polish Zloty from another currency, the exchange rate used was the Norgine 2018 Annual Budgetary Conversion Rate at the time of the transaction, e.g. 1 Euro = 4.2513 PLN equivalent to 1 PLN = 0.2352 Euros. For additional rate conversion including cross rates for 2018, please contact contact@norgine.com.

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. 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 choose to do so, and that further transaction is outside the control of Norgine.

Norgine regularly contracts with advertising agencies, congress organisers 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 ToV made to the individual HCP by these third parties as if the payment had been made directly by Norgine to that HCP (i.e. as an indirect ToV).

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 ToV 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

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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 HCO 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 ToV 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 whether or which HCP has been contracted. ToV 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 ToV 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 ToV. 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.

9. CONTRIBUTIONS TO MEETINGS

Norgine discloses 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 ToV 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.

ToV 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.

ToV made to Polish based organisations by Norgine's overseas operations are disclosed in Poland and Polish Zloty regardless of the source of funding. This means that this



METHODOLOGY NOTES FOR MEDICINAL PRODUCTS

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disclosure contains all ToV that Norgine has made to Polish HCP and HCO, regardless of which Norgine entity has actually made the ToV.

11. CO-MARKETING PROJECTS

Where Norgine jointly markets a product with another pharmaceutical company, Norgine declares the ToV made directly from its own bank accounts and listed in the company financial books as part of its normal business operations. ToV 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

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