



GLOBAL METHODOLOGICAL NOTE FOR PATIENT ORGANISATIONS

Explaining financial support and/or significant indirect/non-financial support or engagement for provision of contracted services related to European Patient Organisations (POrgs)

This document is aligned with the requirements of the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code and intended to guide the readers in understanding how Norgine derives and calculates the amounts presented in their public disclosure for Patient Organisations across Europe, as each pharmaceutical company may approach disclosure in slightly different ways.

1. INTRODUCTION TO NORGINE

Norgine is a leading European specialist pharmaceutical company that has been bringing transformative medicines to patients for over a century. Our commitment to transforming people's lives drives everything we do and our European experience, fully integrated infrastructure and exceptional partnership approach enables us to quickly apply creative solutions to bring life-changing medicines to patients that they may not otherwise be able to access. Norgine is proud to have helped millions of patients around the world in the last few years.

Norgine has a direct presence in 12 European countries, as well as Australia and New Zealand. We also have a strong global network of partnerships in non-Norgine markets. We are a flexible and fully integrated pharmaceutical business, with manufacturing (Hengoed, Wales and Dreux, France), third party supply networks and significant product development capabilities, in addition to our sales and marketing infrastructure. This enables us to acquire, develop and commercialise specialist and innovative products that make a real difference to the lives of patients around the world.

For more information, please visit www.norgine.com or contact us on contact@norgine.com

2. TRANSPARENCY DISCLOSURE AND THE PURPOSE OF THIS DOCUMENT

In Europe, the EFPIA Code requires its member companies to disclose a list of POrgs to which it provides financial support and/or significant indirect/non-financial support or with whom it has engaged to provide contracted services for that Member Company.

The EFPIA Code requires that this disclosure must include a description of the nature of the support or services, provided that it is sufficiently complete to enable the average reader to form an understanding of the nature of the support or the arrangement without the necessity to divulge confidential information.

In addition to the name of the POrg, the following elements are required to be included:

(a) For support:

- the monetary value of financial support and of invoiced costs.
- the non-monetary benefit that the POrg receives when the non-financial support cannot be assigned to a meaningful monetary value.

(b) For contracted services:

- the total amount paid per POrg over the Reporting Period.

The EFPIA Code also requires that each Member Company must publish the methodologies used by it in preparing the disclosures and identifying supports and services provided.

Although Norgine is not a member of EFPIA, in the spirit of transparency and being an ethical organisation, Norgine follows the requirements of the EFPIA Code related to 'Disclosures of Support and Services Provided to POrgs'.

3. FEATURES, BACKGROUND INFORMATION AND METHODOLOGY RELATED TO NORGINE'S PATIENT ORGANISATIONS PUBLIC DISCLOSURE REPORT

Norgine's disclosure report for POrgs is published on its corporate website (www.norgine.com) under the Responsibility tab at the top.

Norgine's disclosure report for POrgs has the following 6 columns:

- Country: indicating the Norgine affiliate generally responsible for providing the data and the territory where the engagement with the POrgs took place
- Registered name of the Patient Organisations
- Nature of Interaction, either listed as:
 - Support: on the basis of an unsolicited request from POrgs to Norgine, and includes grants, donations and fundraising
 - Contracted services: when/if Norgine has proactively approached POrgs for the provision of services benefitting patients
- Descriptor: description of the nature of the interaction that is sufficiently complete to enable the average reader to form an understanding of the significance of the interaction
- Currency
- Amount

The Reporting Period for public disclosures related to POrgs is always one calendar year (Jan to Dec) and is prominently mentioned on individual declaration file. The POrgs disclosure report is published towards the end of March on a yearly basis and covers the 12-month period from January to December covering the preceding year.

Norgine utilises single, consistent transparency standards for disclosing financial support and/or significant indirect/non-financial support to POrgs and for disclosing engagements for the provision of contracted services.

Only one central report is published covering all European POrgs disclosures falling within the remit of the EFPIA Code.

In compliance with the requirements of the EFPIA Code, the information disclosed remains in the public domain for a minimum of 3 years after the time such information is first disclosed.

For non-financial support, a perceived equivalent value to the recipient POrgs is evaluated and stated.

ToVs (see definition) to individual patients who do not represent or are not hired through a POrg are not subject to disclosure.

This document (i.e. Global Methodological Note for POrg) is reviewed yearly in conjunction with the publication of the global POrgs public disclosure report and will be updated only to reflect any changes in the methodology of reporting.

4. DEFINITIONS AND ABBREVIATIONS

Where applicable, Norgine has used the definitions of the EFPIA Code.

Patient Organisation (POrg): non-for-profit legal person/entity (including the umbrella organisation to which it belongs), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is in Europe.

Reporting Period: refers to the annual disclosure cycle and covers a full calendar year.

Donations and Grants: collectively, mean providing funds, assets or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return.

Staff Fund raising: any amount of money raised by members of Norgine staff using Norgine's premises or equipment or time, which is then transferred to a POrg as a donation and grant.

Sponsorship: support provided by Norgine or its behalf, when permitted by law, as a contribution to support an activity (including an Event) performed, organised or created by POrgs. Such support is provided as a result of an unsolicited request from POrgs.

Transfers of Value (ToV): Direct and indirect ToV, whether in cash, in kind or otherwise.

Direct ToVs are those made directly by Norgine for the benefit of a POrg.

Indirect ToVs are those made on behalf of a Member Company for the benefit of a POrg, or those made through a Third Party and where the Member Company knows or can identify the Recipient that will benefit from the Transfer of Value.

5. DATA PRIVACY & CONSENT

Norgine fully supports the concepts of transparency and applicable regulations including data protection laws. Provision of financial support and/or significant indirect/non-financial support to POrgs or engagement for the provision of contracted services is always captured in a contract which clearly states the requirement to publicly declare both financial support and/or significant indirect/non-financial support or fee for the provision of contracted services received by the POrgs. Where needed, consent for the publication of the ToVs is obtained and documented within the underlying contract before disclosing the data on an individual POrg level.

6. TRANSACTIONS

Transaction Date versus Service Delivery Date

Norgine handles and declares the ToV from the time of payment to the POrgs, 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 ToV undertaken in one Reporting Period are reported in the next Reporting Period, and vice versa.

ToV will always be paid after the engagement has taken place, with the exception of grants (see definition) that will be paid before the event actually takes place.

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.

Handling of Currency and Exchange Rates

The values in the disclosure template are expressed in local currency. Where values had to be converted into local currency from another currency, the exchange rate used is clearly stated in individual declaration document.

7. CROSS-BORDER PAYMENTS

Norgine has Affiliates in many countries within and outside the European Union. Norgine applies the EFPIA definition of cross-border ToVs as being a ToV to a POrg that is registered **outside** the country where the Norgine affiliate, who has provided the funding is based. In general, where local law requires, such ToVs are disclosed in the local currency of the country where the POrg has been formally registered.

8. FURTHER INFORMATION

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

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