

## **NORGINE and Patient Organisations**

### **Basis of Cooperation and Guiding Principles**

#### **Basis of Cooperation**

NORGINE is committed to improving patient health care and medical services, working together with patient organisations ("Patient Organisations") which advocate for and/or support the needs of people affected by medical conditions throughout the world. In connection therewith, NORGINE takes seriously its responsibility to comply with its ethical and legal obligations. This document establishes the governing principles of such cooperation which have been adopted by all NORGINE entities within the NORGINE group and apply to all conduct between NORGINE and existing and prospective Patient Organisations, wherever the geographic location of the Patient Organisation.

The working relationship shall be founded upon the following NORGINE central principles ("**NORGINE Principles**"), which serve as a link between country laws, regulations and industry guidelines:

- A mutually beneficial relationship based on honesty, respect and trust, with the views of each partner having equal value;
- The objectives and scope of the partnership will be transparent and reflected in the form of a written agreement;
- A commitment to facilitating agreed objectives with appropriate resources;
- Services should only be provided to companies for the purpose of supporting healthcare or research;
- A recognition of and appreciation for independence and autonomy in terms of each party's political judgement, policies and activities;
- Compliance with applicable laws, regulations and codes of conduct;
- The highest professional and ethical standards in all activities;
- Regular review and accountability with respect to the scope of the partnership, its objectives and benefits;
- Material and information produced and distributed jointly shall be objective and factually accurate, approved by each party in accordance with its own editorial and advisory policies; and
- All parties are fully aware that sponsorship must be clearly acknowledged and apparent from the start. NORGINE shall make relevant information publicly available concerning this cooperative relationship with the Patient Organisation on the NORGINE website, and in other appropriate media in its reasonable discretion, generally disclosing the nature of its working relationship and payments or benefits in kind made by NORGINE relating thereto, including specific information as appropriate, which is updated annually.
- The Patient Organisation is obliged to declare that they have provided paid services to NORGINE whenever they might write or speak publicly on any topic related to the Agreement or any other issue relating to Norgine.

Each party retains the right to work with and receive support from other organisations in relation to the agreed goals and other objectives.

#### **Application of the NORGINE Principles**

All NORGINE partnership programmes with Patient Organisations will comply with applicable national regulations world-wide and industry codes of conduct including the International Federation of Pharmaceutical Manufacturers & Associations Code of Pharmaceutical Marketing Practices. All agreed activities undertaken by NORGINE and Patient Organisations shall be consistent with relevant best practice guidelines and codes of conduct in the territory governing these relationships.

All NORGINE working relationships with Patient Organisations will be transparent, declared publicly on an annual basis in appropriate media and shall be subject to terms and conditions set forth in a written agreement. This written agreement must be certified or examined in accordance with the appropriate internal approval procedures and will set out the agreed activities, including the terms and conditions regarding the relationship and the funding for every significant activity or ongoing relationship, and the approval process of each party. Whilst these working relationships are broadly defined, including providing information to support the work of the Patient Organisation, sponsoring materials and meetings, and providing financial support, clarity is essential. Core funding and unrestricted grants require a written statement to that effect, as well as setting forth other material aspects of the basis of cooperation.

NORGINE provides funding and other professional assistance to Patient Organisations on the express condition that activities and information intended for public distribution must comply with all applicable guidelines, codes of conduct and laws and the NORGINE Principles. NORGINE reserves the right to immediately withdraw a Patient Organisation's funding upon written notice delivered to the Patient Organisation if an activity does not comply. Every individual programme or series of related activities that is undertaken as part of NORGINE's association with the Patient Organisation will be the subject of a written agreement with NORGINE and will be formally reviewed and certified by NORGINE.

Templates of agreements covering NORGINE's specific cooperative relationships with Patient Organisations (Schedule I) and its core funding and unrestricted grants (Schedule II) are attached. These are intended as model formats to facilitate and ensure compliance. Whilst each of NORGINE's agreements may be tailored to meet the specific requirements of a Patient Organisation and the complexity and duration of the project, all agreements will include the essential elements contained in the relevant template.

Agreed on behalf of **NORGINE Danmark A/S**

Name: Niklas Eriksson

Role: General Manager

Signature: 

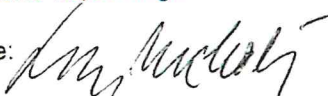
Date: 28/02/2018

Agreed on behalf of **Leverforeningen**

Name: Lone McColaugh



Role: Landsformand

Signature: 

Date: 01/03/2018



## Schedule Agreement - Sponsorship of Specific Joint Activities

This Agreement is entered between Norgine Danmark A/S, having offices at Lyskaer 1, 3<sup>rd</sup> floor, DK-2730 Herlev ("NORGINE") and Leverforeningen having offices at Alækkehaven 30, 5000 Odense C and sets forth the basis of collaboration between NORGINE and Leverforeningen. NORGINE and Leverforeningen are each referred to as a "Party" and collectively as the "Parties", each referred to as a "Party" and collectively as the "Parties". The Parties agree to cooperate and support the project described below (the "Project") in accordance with Norgine and health care professionals guiding principles ("Norgine Principles"), and confirms that he/she has obtained all required approvals and consents in order to enter and perform into this agreement. The Agreement is valid when signatures from both Norgine Danmark A/S and Leverforeningen have been obtained.

Name of the Project	Advertisement in member magazine and on webpage <a href="http://www.leverforeningen.dk">www.leverforeningen.dk</a> in 2018
Names of all the partnering organisations or associations participating in the Project	Norgine Danmark A/S and Leverforeningen
Type of Project	Norgine advertisement in member magazine and <a href="http://www.leverforeningen.dk">www.leverforeningen.dk</a> . Non-product related.
Summary of Scope and Intended Objectives	Buy space for company advertisement and financial support to Leverforeningen
Agreed role of each party	Norgine will provide relevant logo and advertisement for member magazine
Timeframe for the Project (start date & finish date)	Levernyt is published 4 x annually
Amount and nature of financial support of Norgine	Advertisement x 4 total DKK 12.000,- Sponsorship for daily operation total DKK 23.000,-
Payment Schedule	Payment will be done when this agreement has been signed by both parties and the form with payment information has been returned
Anticipated amount and nature of non-financial support of NORGINE, Leverforeningen and any partners	N/A
Description of how NORGINE Project resources/costs will be monitored	Payment will be done as outlined above
Terms and conditions relating to NORGINE's use of Leverforeningen's logo and proprietary material, if applicable, including without limitation, permitted purpose and manner of such use and any express limitations.	N/A
Country Code(s) of Practice that will apply	Lægemiddelindustriforeningens patientforeningskodeks
Decision making process of the Project	Norgine advertisement will be approved internally before sending to Leverforeningen
Norgine contact	Niklas Eriksson, General Manager <a href="mailto:neriksson@norgine.com">neriksson@norgine.com</a>

Leverforeningen contact	Landsformand Lone McColaugh / formand@leverforeningen.dk
Management of the Project - designate responsibility for key objectives	Niklas Eriksson
Review of the Project- describe process of evaluating whether objectives have been achieved	Norgine will ensure that objectives have been achieved

Each Party declares that the material or arrangements will be certified where required or examined in accordance with the appropriate internal approval procedures. All Parties are fully aware that acknowledgment of the support described herein must be prominently displayed from the start.

NORGINE may terminate this Agreement immediately by written notice to [Leverforeningen](#) in the event that [Leverforeningen](#) does not comply with the terms of this Agreement, applicable laws, regulations and NORGINE Principles. This Agreement shall be governed by and construed in accordance with the laws of Denmark and the Parties hereto hereby submit to the exclusive jurisdiction of the courts of Denmark.

This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of the Agreement, and all of which when taken together shall be deemed to constitute one and the same agreement. Signatures to this Agreement transmitted by facsimile transmission, by electronic mail in "portable document format" (.pdf) form, or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, will have the same effect as physical delivery of the paper document bearing the original signature.

This Agreement is entered into as of the date referenced above and may only be amended in writing by duly authorised representatives of each of the Parties.

Norgine Danmark A/S

Signature 

Name Niklas Eriksson

Title: General Manager

Date: 28/02/2018

Organisation: [Leverforeningen](#)

Signature 

Name: [Lone McColaugh](#)

Title: [Landsformand](#)

Date: 01.03.2018



## Norgine and Organisations Norgine Principles

Norgine is committed to working in a professional manner with and utilising the services of healthcare professionals or healthcare organisations comprised of healthcare professionals and appropriate administrative staff or other relevant decision makers (collectively "HCOs") in various capacities as consultants and advisors, or to support specific activities and projects, whether in groups or individually, to provide services in order to promote patient healthcare and medical services and education in accordance with applicable codes of practices e.g. IPFMA, EFPIA, MEDTECH or applicable laws (and in the case of conflict with the more onerous of the applying).

Norgine takes seriously its responsibility to comply with its ethical and legal obligations. This document establishes the governing principles of Norgine arrangements with HCOs and implements procedures to ensure compliance with applicable national regulations world-wide and applicable industry codes of conduct. The working relationship shall be founded upon the following Norgine central principles ("Norgine Principles"), which serve as a link between country laws, regulations and industry guidelines. The Norgine Principles have been adopted by all Norgine entities within the Norgine group and apply wherever the geographic location of the HCO and to all relationships with HCOs excluding only research services, where separate arrangements apply.

The Norgine Principles are:

- Norgine will only use the services of or cooperate with HCOs where there is a genuine need for these services and the people employed are suitable and / or there is a mutual interest and benefit deriving from the cooperation for both parties;
- Prior to the commencement of any services or cooperation, the parties shall conclude a written agreement specifying the nature of the services or cooperation and the basis and the amount of any payment or transfer of value (as defined in applicable laws, whether in cash or in kind and including without limitation direct or indirect transfers of anything of value, such as compensation, reimbursement for expenses, meals, travel, medical journal reprints, medicinal products or supplies, or medical writing and publications assistance);
- Prior to the engagement of or starting of the cooperation with HCOs, Norgine will conduct appropriate and proportionate due diligence and associated risk assessments for all HCOs involved with the services, in accordance with Norgine policies and applicable laws. Particular attention shall be paid to HCOs who are also public officials, and Norgine will not offer or make any payments or transfers of value to any official or other person that is intended or could be seen, to influence any decision to obtain or retain business, to gain an improper advantage, or to induce such official or other person to perform a function in violation of any statute, rule, or regulation.
- Any payments or transfers of value to HCOs in respect of the services or the cooperation must be made pursuant to written agreements.
- Compensation paid to HCOs for performance of the services or the cooperation will be determined according to a centrally managed, pre-set rate structure that is fair, reasonable and reflects the current market value of the agreed services;
- Norgine shall comply with applicable laws, regulations and applicable codes of conduct (including data protection requirements) in relation to its interactions with HCOs;
- Norgine shall ensure that the highest professional and ethical standards shall be adhered to in respect of any services provided or activities conducted by HCOs;
- Norgine shall monitor compliance with the Norgine Principles and applicable laws by way of regular reviews, and accountability with respect to the scope of the services performed or the activities conducted and the payments received;
- Norgine shall disclose publicly (including disclosure on Norgine websites and/or third party or authorities' websites or in other appropriate media) the nature of its working

relationships with HCOs to the extent required by applicable laws and codes of practice. This may include relevant specific information about payments, donations, grants or benefits in kind made by Norgine in connection with these relationships, including the names of individual HCOs. Such information may be transferred to relevant industry bodies, other Norgine affiliates and/or to third parties providing services to Norgine (each of whom may be established in or outside the jurisdiction in which the services are provided).

- If an HCO does not consent to public disclosure of his or her personal details, Norgine may refuse to enter into any proposed agreements for the provision of services, or may opt to disclose the value of any payments or transfers of value made in question on an anonymous basis (in aggregate form or otherwise).
- Norgine shall use the services of or cooperate with HCOs only where it is able to do so in accordance with the applicable laws and codes.
- Norgine shall ensure that any hiring of any HCOs to perform services or any cooperation with any HCOs does not amount to an inducement to prescribe, supply, administer, recommend, buy or sell any medicine of Norgine.
- Norgine shall maintain accurate records relating to services provided by HCOs and payments and transfers of value made to HCOs and shall retain such documentation for so long as may be required by applicable laws or code of practice.
- All reports concerning safety related information including Adverse Events and Special Situations received by HCOs on Norgine's Products must be transmitted to Norgine within One (1) Calendar Day after receipt. The transmission of information will be in accordance with the contact details set forth in Appendix A.
- Any problems concerned with a Norgine Device must be transmitted to Norgine within One (1) Calendar Day of receipt. The transmission of information will be in accordance with the contact details set forth in Appendix A.

#### Application of the Norgine Principles

Norgine enters into agreements with HCOs and provides funding and other support to HCOs on the condition that the HCOs will also adopt and comply with the Norgine Principles, all applicable laws, regulations and applicable codes of conduct and confirms that he/she/they has/ve obtained all necessary approvals or authorisations from any employer or institution with which he/she/they is/are affiliated. Norgine will inform the HCOs that he/she/they is/are obliged to declare that he/she/they is/are a consultant to Norgine whenever he/she/they write(s) or speak(s) in public about a matter that is the subject of the agreement with Norgine or any other issue relating to Norgine. Similarly, HCOs who provide consultancy services to Norgine and are still practising their profession are obliged to declare their consultancy with Norgine whenever they write or speak publicly about a matter that is the subject of the consultancy or any other issue relating to Norgine.

Norgine reserves the right to immediately terminate the services of or withdraw from the cooperation with the HCO upon written notice delivered to the HCO where Norgine believes that the HCO is not abiding by the Norgine Principles or the terms of any separate agreement between the parties.

Agreed on behalf of Norgine Denmark  
A/S


Signature 

Name: Kenneth Scrimgeour

Title: Chief Commercial Officer

Date: 8/12/17

Agreed on behalf of Leverforeningen

Signature 

Name: Lone McColaugh

Title: Chairman

Date: 13.12.2017



## Schedule

### Agreement - Sponsorship of Health Care Organization(s) for Specific Joint Activities

This Agreement is entered between Norgine Denmark A/S, having offices at Lyskær 1, 3.th, DK-2730 Herlev and Leverforeningen, Aløkkehaven 30, DK-5000 Odense C, and sets forth the details of the services Lone McColaugh shall provide to Norgine (the "Services"). Norgine and Leverforeningen are each referred to as a "Party" and collectively as the "Parties". Leverforeningen agrees to provide the Services in order to complete the project described below (the "Project") in accordance with Norgine and healthcare professionals guiding principles ("Norgine Principles"), and confirms that he/she has obtained all required approvals and consents in order to enter and perform under this Agreement. The Agreement is valid when signatures from both Norgine Denmark A/S and Leverforeningen have been obtained

Name of the Project	Advertisement in member magazine and on webpage <a href="http://www.leverforeningen.dk">www.leverforeningen.dk</a>
Names of all the partnering organisations or associations participating in the Project	Norgine Danmark A/S and Leverforeningen
Type of Project	Norgine advertisement in member magazine and <a href="http://www.leverforeningen.dk">www.leverforeningen.dk</a> . Non-product related
Summary of Scope and Intended Objectives	Buy space for company advertisement and financial support to Leverforeningen.
Agreed role of NORGINE, Leverforeningen and each partner	Norgine will provide relevant logo and advertisement for member magazine
Timeframe for the Project (start date & finish date)	Levernyt is published 4 x annually
Amount and nature of financial support of Norgine	Advertisement x 4 total DKK 12.000,- Sponsorship for daily operation total DKK 23.000,-
Payment Schedule	Payment will be done when this agreement has been signed by both parties and the form with payment information has been returned.
Anticipated amount and nature of non-financial support Leverforeningen and any partners	N/A
Description of how NORGINE Project resources/costs will be monitored	Payment will be done as outlined above
Terms and conditions relating to NORGINE's use of Leverforeningen's logo and proprietary material, if applicable, including without limitation, permitted purpose and manner of such use and any express limitations.	N/A
Country Code(s) of Practice that will apply	Lægemiddelindustriforeningens patientforeningskodeks
Decision making process of the Project	Norgine advertisement will be approved internally before sending to Leverforeningen.
Norgine contact	Brand Manager Ann Kajson Carlqvist <a href="mailto:akajsoncarlqvist@norgine.com">akajsoncarlqvist@norgine.com</a>

NOR/COR/1217/0583

Organisation name	Landsformand Lone McColaugh formand@leverforeningen.dk
Management of the Project - designate responsibility for key objectives	Ann Kajson Carlqvist
Review of the Project- describe process of evaluating whether objectives have been achieved	Norgine will ensure that objectives have been achieved

Each Party declares that the material or arrangements will be certified where required or examined in accordance with the appropriate internal approval procedures. All Parties are fully aware that acknowledgment of the support described herein must be prominently displayed from the start.

NORGINE may terminate this Agreement immediately by written notice to [Leverforeningen](#) in the event that [Leverforeningen](#) does not comply with the terms of this Agreement, applicable laws, regulations and NORGINE Principles. This Agreement shall be governed by and construed in accordance with the laws of Denmark and the Parties hereto hereby submit to the exclusive jurisdiction of the courts of Denmark

This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of the Agreement, and all of which when taken together shall be deemed to constitute one and the same agreement. Signatures to this Agreement transmitted by facsimile transmission, by electronic mail in "portable document format" (.pdf) form, or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, will have the same effect as physical delivery of the paper document bearing the original signature.

This Agreement may only be amended in writing by duly authorised representatives of each of the Parties.

Norgine Denmark A/S


Signature 

Name: Kenneth Scrimgeour

Title: Chief Commercial Officer

Date: 8/12/17

Organization: [Leverforeningen](#)

Signature 

Name: Lone McColaugh

Title: Chairman

Date: 13.12.2017



## Appendix A

"Adverse Event" is any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product, which does not necessarily have to have a causal relationship with this treatment. An Adverse Event can therefore be any unfavorable and unintended sign (e.g. an abnormal laboratory finding), symptom or disease temporally associated with the use of a medicinal product, whether or not considered related to this medicinal product. In the context of clinical trials, an AE will also mean events associated with and/or possibly attributable to the clinical trial protocol design or clinical trial procedures.

"Special Situations" means those situations requiring reporting in addition to routine expedited and periodic reporting and currently defined in GVP Module VI (Management and reporting of adverse reactions to medicinal products) as:

- Reporting of outcomes of use of a medicinal product during pregnancy and breastfeeding;
- Reporting of lack of therapeutic efficacy;
- Reporting in relation to overdose, abuse, off-label use, misuse, medication error or occupational exposure;

In addition to the situations defined above, Special Situations in this Agreement will also

- Reporting following suspension or withdrawal of the marketing authorisation for safety or commercial reasons;
- Reporting from compassionate/named patient use;
- Reporting of suspected transmission of infectious agents;
- Reporting in the event of a public health emergency.

"Device Event" is defined as any problems that arise from the use of the Device;

"Calendar Day 0" means the date when any of the Parties', Affiliates or organisation with whom either Party has a contractual agreement, is notified of, or comes into possession of safety information which contains minimum information to constitute a valid case as defined by the Applicable Laws.

### Local Pharmacovigilance Contact details

Medical Director Mogens Gisselbaek  
Email: [MInfoNordic@norgine.com](mailto:MInfoNordic@norgine.com)  
Tel: +45 5317 0400