

## **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: Peter Legarth

Role: General Manager


Signature: 

Date: 15.10.09

Agreed on behalf of Leverforeningen

Name: Lone McColaugh

Role: Landsformand

Signature: 

Date: 09.10.2015

### Schedule I Model Template- Sponsorship of Specific Joint Activities

This Agreement is entered into 7th of October 2015 between Norgine Denmark, having offices at Lyskær 1, 3 th, 2730 Herlev ("NORGINE") and Leverforeningen, having offices at Aløkkehaven 30, 5000 Odense C ("Leverforeningen"), 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". The Parties agree to cooperate and support the project described below (the "Project") in accordance with NORGINE and Patient Organisations Basis of Cooperation and Guiding Principles ("NORGINE Guidelines").

<b>Name of the Project</b>	Participate at the launch of the Time to DeLiver: Getting a Grip on HE (hepatic encephalopathy) report on 12th October 2015 at the European Parliament in Brussels.
<b>Names of all the partnering organisations participating in the Project</b>	Leverforeningen and Norgine
<b>Type of Project</b>	Financial support
<b>Summary of Scope and Intended Objectives</b>	At the event Leverforeningen will get: <ul style="list-style-type: none"> <li>• a presentation of the report including objectives, facts , and a summary of the calls to action</li> <li>• The clinical perspective including the clinical significance of HE and insights into the care needs of HE patients</li> <li>• The patient perspective including real-life experience of living with HE from a patient and their family/carers</li> <li>• The opportunity to meet and discuss the topic with other patient organisations, politicians etc.</li> </ul>
<b>Agreed role of NORGINE, Leverforeningen and each partner</b>	Norgine: financial support Leverforeningen participate
<b>Timeframe for the Project (start date &amp; finish date)</b>	7 <sup>th</sup> of October – 13 <sup>th</sup> of October 2015
<b>Amount and nature of financial support of NORGINE</b>	9,000 DKK (transportation, meals and accommodation costs)
<b>Payment Schedule</b>	Payment will be done when this agreement has been signed by both parties and the form with payment information has been returned.
<b>Anticipated amount and nature of non-financial support of NORGINE, Leverforeningen and any partners</b>	Not applicable
<b>Description of how NORGINE Project resources/costs will be monitored</b>	Payment will be done as outlined above
<b>Terms and conditions relating to</b>	Not applicable





NORGINE's use of Leverforening's logo and proprietary material, if applicable, including without limitation, permitted purpose and manner of such use and any express limitations.	
Country Code(s) of Practice that will apply	ENLI's patient codex as defined in reklamebekendtgørelsens § 1, stk. 71
Decision making process of the Project	Not applicable
NORGINE CONTACT	Jens Rovelt Andreasen jandreasen@norgine.com
Leverforeningen CONTACT	Lone McColaugh formand@leverforeningen.dk
Management of the Project-designate responsibility for key objectives	Jens Rovelt Andreasen
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 Guidelines. This Agreement shall be governed by and construed in accordance with the laws of Lægemiddeloven 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 Denmark**

**Leverforeningen**

By   
 Name: Peter Legarth  
 Title: General Manager

By   
 Name: Lone McColaugh  
 Title: Landsformand

15.10.09

09.10.2015