RECOMMENDED GUIDELINES
BETWEEN THE NORWEGIAN FEDERATION OF ORGANISATIONS OF DISABLED PEOPLE (FFO) and THE NORWEGIAN ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS (LMI)

for
contact and cooperation between patient oganisations and the pharmaceutical industry

The agreement, objectives and parties

These guidelines lay down the framework for cooperation between members of the Norwegian Association of Pharmaceutical Manufacturers (LMI) and patient organisations associated with the Norwegian Federation of Organisations of Disabled People (FFO).

FFO is the umbrella organisation for organisations of disabled and chronically ill people. FFOôs overarching goal is social equality and participation for the disabled and chronically ill. The organisations works to make the everyday life of disabled and chronically sick people better.

LMI is a trade organisation for pharmaceutical manufacturers. LMIôs members account for the bulk of sales of medicinal products in Norway. LMI works for the framework conditions of the members and for recognition of the importance of medicinal products for quality of life, health and well being.

By means of these guidelines, FFO and LMI wish to contribute to full transparency regarding all cooperation between patient organisations and pharmaceutical companies. The purpose of the cooperation shall always be the promotion of professional activities and interest policies.

The guidelines are also intended to strengthen and regulate the partiesô work to improve the treatment options of the chronically ill and disabled through good, rational and professional cooperation.

All cooperation between the parties shall take place in such a way that neither society nor the patients can cast doubt on the independence or the integrity of the organisations or the employees of the companies. This makes special demands with respect to transparency and the possibility of surveillance in connection with signed agreements and interaction. Interaction shall be characterised by orderliness, openness and transparency.

Scope

Cooperation between LMI companies and patient organisations shall be in accordance with currently applicable national and international rules and regulations and recognised guidelines. For LMI members, special reference is made to the industryôs own self-imposed ôRules governing drug informationô. These guidelines are partly based on the rules laid down in the European Federation of Pharmaceutical Industries Associationsô (EFPIA) ôCode of practice on relationships between the Pharmaceutical Industry and Patient Organisationsô of

October 2007. These guidelines do not preclude companies and/or organisations from having their own, more rigorous rules for cooperation.

ôOrganisationsô in this document means patient and patient organisations associated with FFO.

The term ôLMI companyô/ôpharmaceutical companyô covers any entity that provides financial support to or involves itself in relation to a patient organisation or employees in such organisations, whether the entity is a head office with its base abroad, a subsidiary or any other form of national or international operation (including sole traders) that are associated with a company that is a member of LMI or of its European representative body, EFPIA.

The agreement also covers external contractors (such as PR, advertising and marketing agencies and consultants) who are used in connection with joint cooperative projects. In such cases, it is the pharmaceutical industryôs responsibility to ensure that rule and guidelines are observed.

1

Prohibition of marketing of prescription pharmaceuticals

National and international rules that prohibit the marketing of prescription pharmaceuticals to the general public apply.

2

Written agreements

Agreements between patient organisations and the pharmaceutical industry shall be written and the amount of financial support, the purpose of the support, and what it is to be used for shall be specified. In cases where general or specific support is given to the organisationsô work or to organisation employees, details and grounds shall be supplied. The same applies in those cases where the pharmaceutical industry provides project-based support. Written agreements shall also be entered into if significant non-financial support is provided by the pharmaceutical industry to the patient organisations or their employees. In these cases, too, an account shall be given of the purpose of the support.

See also Appendix 1 to these guidelines (Proposed template for agreement between the pharmaceutical industry and the patient organisations).

All pharmaceutical companies shall have an approval process for entry into and renewal of agreements between the company and patient organisations.

3

Use of logo and other material belonging to the parties

The use of a patient organisationôs logo shall be approved by the patient organisation. When the pharmaceutical company applies for such permission, the purpose and manner in which it is intended using the logo shall be made clear. This also applies when a company logo is used. Such use shall be approved by the pharmaceutical company. Logos shall be used in such a way that no notions are created of dependency between the patient organisation and the pharmaceutical company.

4

The independence of the patient organisations

In connection with financial or non-financial support from the industry, no guidelines shall be stipulated for the professional or interest policy views of the patient organisation. When the pharmaceutical industry provides financial support to patient organisations, no guidelines shall be stipulated for the text or design of the patient organisationsômaterial in a manner that promotes the commercial interests of the company/companies.

The pharmaceutical company may provide financial support to the secretariat function of a patient organisation, but may not take over its practical administration. This could give rise to questions concerning the integrity of the organisation. It shall always be clear who is supporting the function/programme.

5

Transparency

The agreements shall be publicly available, so that no notions are created of unfortunate links between industry and patient organisations.

Each pharmaceutical company shall have publicly available a list of patient organisations that receive financial support and/or special non-financial support. The list shall contain a brief description of the type of support that is provided. This information shall be available at national or European level, and shall be updated at least once a year.

The pharmaceutical companies must ensure that their financial and/or non-financial support is always acknowledged and open/available to the general public.

6

Prohibition of exclusivity agreements

No exclusivity agreements may be made. Patient organisations shall be free to cooperate with more than one pharmaceutical company. The pharmaceutical companies shall also be free to cooperate with one or more patient organisations. No agreements shall be made that secure overall exclusive rights, or that contribute to exclusive rights within a product area. This shall nevertheless not preclude a patient organisation from having a primary cooperative partner.

7

Arrangements and hospitality

All arrangements that are sponsored or organised by or on behalf of a pharmaceutical company shall be held in a manner that is consistent with the requirements of professionalism and transparency. Destinations that are renowned for their entertainment facilities or extravagance shall be avoided.

All forms of hospitality (dinners etc.) from the pharmaceutical industry to patient organisations shall be of a restrained nature, and shall not account for a major part of the financial support provided by the pharmaceutical industry. This applies whether the arrangement is organised by the patient organisations themselves or by the pharmaceutical industry.

In connection with arrangements, entertainment costs covered by the pharmaceutical company to the patient organisations or their employees shall be limited to travel expenses, meals, accommodation and registration fees.

Pharmaceutical companies shall not organise or provide financial support for arrangements that take place outside the home country of the patient organisations except in those cases where:

a) the majority of the invitees come from other countries and, given the countries of origin of the participants, it (therefore) makes greater logistical sense to hold the arrangement in another country.

b) the arrangement is held abroad because experts who are to play a part in the arrangement are from/in the country in question.

In connection with financial support or cooperation with patient organisations, pharmaceutical companies shall always ensure that the activity is not in conflict with government or the pharmaceutical industryôs own rules concerning information.

8

Partiality

To ensure that no notions are created concerning inappropriate connections, the following precautions shall be taken:

Employees or elected officers of patient organisations shall not carry out assignments for the industry without this first being reported to superiors or officers of the organisation. Agreements may not be entered into concerning assignments where partiality or independence can justly be questioned.

Pharmaceutical industry employees shall not hold offices in patient organisations unless it is clear that there are no inappropriate connections.

No agreements concerning financial support may be entered into between the pharmaceutical industry and individuals or elected officers of patient organisations. This shall not prevent

agreements concerning professional assignments being made between individuals associated with the patient organisations and the pharmaceutical industry.

There shall always be complete transparency concerning matters that are mentioned in these guidelines.

9

Entry into force and compliance

This agreement consists of recommended guidelines that the parties urge the individual member companies and member organisations to follow.

The guidelines are binding for the member companies of LMI, EFPIA and their employees. LMI companies are also bound by the industryôs internal, self-imposed ôRules governing drug informationô, in which rules concerning surveillance and compliance are laid down.

FFO and LMI shall work together to ensure that the guidelines in this document are followed.

These guidelines enter into force on 1 June 2008.

Oslo, 17 April 2008

For Norwegian Federation of Organisations of Disabled People (FFO)	For The Norwegian Association of Pharmaceutical Manufacturers (LMI)
Margaret Sandøy Ramberg Chairman	Pål Christian Roland CEO

Appendix 1:
Draft agreement between pharmaceutical company and patient organisation

APPENDIX 1: Proposed template for written agreements between the pharmaceutical industry and patient organisations

Agreement between *(patient organisationôs name)* and *(pharmaceutical companyôs name)*

When pharmaceutical companies provide financial support, significant indirect support and/or significant non-financial support to patient organisations, the agreement shall be set out in writing.

The following is a proposed template for such written agreements. The draft can be used in its entirety or adapted where appropriate. The intention is to reflect what has been agreed, and to take account of the laws and rules upon which such agreements shall be based.

As a minimum, an agreement between the pharmaceutical industry and patient organisations shall contain:

1) The name of the cooperative project
2) The name of the parties that have entered into the agreement (name of the pharmaceutical company, name of the organisation and name of any third party (contracting third party: PR agency, market research agency etc.)
3) Type of project or other form of support (i.e. whether it is a general operations subsidy, support for a limited project, specific meetings, sponsorship, information campaigns, support for courses, congresses, travel, stipends to an organisation or an individual alone or on behalf of the organisation).
4) Purpose
5) The part played by the parties in the cooperation
6) Time frame
7) The amount of the financial support and what it is to be used for
8) Scope and content of indirect support or non-financial support (for example support for PR activities, free courses, office support, free rental of premises etc.)

All parties are aware that there shall be complete openness concerning financial and other support from the pharmaceuticals industry to the patient organisations.

Place and date of making the agreement

The agreement's signatories

For pharmaceutical company x

For patient organisation y