RULES GOVERNING DRUG INFORMATION

As laid down on 15 November 1994 by the General Assembly of the Norwegian Association of Pharmaceutical Manufacturers including later revisions, the most recent at the General Assembly on 25 March 2008.

1. INTRODUCTION

1.1 The main responsibility of the Pharmaceutical Industry is to develop new and efficient medicinal products, to improve existing medicinal products, and to provide information to assure that these products will be of use to the individual patient.

The Industry, therefore, in addition to other marketing activities, should organise professional meetings and contribute to the continuous improvement of the level of competency in the public health service. Such events are to be characterised by a high professional quality, and otherwise be of a modest standard.

The marketing of medicinal products will be carried out in accordance with the rules described in this document.

1.2 All members of the Norwegian Association of Pharmaceutical Manufacturers have a duty to comply with the Rules governing Drug Information as laid down by the Association. All pharmaceutical companies have a duty to provide health personnel with relevant, reliable and adequate information about the medicinal products they bring to market.

1.3 The Rules are based on the Code of practice adopted by the European Confederation of Pharmaceutical Manufacturers (EFPIA), which is the representative body for the European pharmaceutical industry and to which the Norwegian Association of Pharmaceutical Manufacturers is affiliated. The latest version of EFPIA’s Code of Practice on the Promotion of Medicines was adopted by EFPIA 5. October 2007 and will take effect no later than 1 July 2008. The code has been revised to make it fully consistent with Directive 2001/83/EC and Directive 2004/27/EC. The Rules also include regulations resulting from agreements of cooperation between LMI and the Norwegian Medical association and between LMI and the Regional Health enterprises. Reference is also made to the agreements between LMI and the Norwegian Nurses Organisation (NSF), the Norwegian Pharmacist Association and agreement between LMI and the Norwegian Federation of Organisations of Disabled People (FFO). Moreover, reference is made to public laws and regulations.

1.4 The Norwegian Association of Pharmaceutical Manufacturers, together with the Norwegian Medical Association, have established the Committee for Drug Information which acts as a voluntarily and self-regulating supervisory body for all members of both associations. The Committee’s functions include ensuring that the Rules governing Drug Information are observed.
1.5
In the event of doubt about the interpretation of the Rules governing Drug Information, decisive importance shall be attached to how similar matters have been decided or practised under the prevailing Council Directive and under the Code of Practice on the Promotion of Medicines as laid down by EFPIA.

2. SCOPE OF THE RULES – DRUG INFORMATION

2.1
The Rules apply to every form of marketing. This entails any information and sales promotion activity carried out by, or on behalf of, a pharmaceutical manufacturer, and conducted in a form that is designed to influence the prescribing, turnover, sale and consumption of the company’s medicinal products.

The Rules apply to all forms of communication between manufacturers/suppliers and health personnel or the general public.

The Rules apply to every form of marketing, including advertising in trade periodicals and direct marketing, the activities of pharmaceutical company representatives, the use of audio-visual systems such as film, video recordings, database services and the like, and the distribution of drug samples, gifts and coverage of expenses. The Rules are not intended to restrict the exchange of medical and scientific information while a product is being developed.

2.2
The Rules do not apply to:

Labelling and packaging enclosures, or the summary of product characteristics (SPC), which is approved on the issue of a marketing licence.

The correspondence, and any other material of a non-marketing nature, needed to reply to specific questions about a specific pharmaceutical product.

Specific and informative public notifications concerning, for example, new packaging, warnings of possible side-effects, as well as product catalogues and price lists, provided that these do not contain any product information.

Statements relating to human health or illness provided that no direct or indirect reference is made to pharmaceuticals.

Clinical trials, including non-intervention trials, are not within the scope of the Rules. Reference is made to separate guidelines for non-intervention trials adopted by LMI.

3. MARKETING

3.1
A medicinal product may be marketed when a marketing licence has been issued, and price approved (cf. Regulation relating to pharmaceuticals § 13-7).
3.2
Marketing must be in conformity with the information stated in the approved summary of product characteristics.

3.3
Marketing must be in accordance with public regulations and laws.

3.4
Compliance with the provisions of clause 3.2 above is not required if the advert is only intended to serve as a reminder, provided the advert contains only the name of the product, the generic name of the components, and the name of the marketing agent.

3.5
Marketing must maintain high quality and must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry and not be likely to cause offence.

3.6
Promotion should only be directed at those who’s need for, or interest in, the particular information can reasonably be assumed.

3.7
Mailing lists must be kept up-to-date. Requests by healthcare professionals to be removed from promotional mailing lists must be respected. All registration of personal data on health personnel must be in accordance with prevailing rules.

3.8
Subject to applicable national laws and regulations, the use of faxes is prohibited except with the prior permission, or upon the request, of the recipient.

3.9
As a general rule, sales representatives from the pharmaceutical industry should hold meetings with groups of health professionals. This does not preclude holding meetings with individual health professionals for practical reasons.

4. INFORMATION AND DOCUMENTATION

4.1 Information
Pharmaceutical information shall be exact, balanced, truthful and objective, and sufficient to enable the recipient to form an opinion about the therapeutic value of the product in question. The information should be based on the most recent evaluation of scientific material and should clearly reflect this material. The information shall not be misleading as a result of distortions, incorrect assertions, omissions etc.
All illustrations used in promotion should clearly indicate the precise source(s). Where adaptation or modification is required it must be clearly stated that the artwork has been adapted and/or modified. Particular care must be taken to ensure that artwork included in
promotion does not mislead about the nature of a medicine or mislead about a claim or comparison.

The word “safe” must never be used to describe a medicinal product without proper qualification.

The word “new” must not be used to describe any product or presentation which has been generally available or any therapeutic indication which has been generally promoted, for more than one year.

It must not be stated that a product has no side-effects, toxic hazards or risks of addiction or dependency.

Quotations from medical and scientific literature must be faithfully reproduced and the precise sources identified.

Any comparison made between different medicinal products must be based on relevant and comparable aspects of the products. Comparative advertising must not be misleading or disparaging.

4.2 Documentation

All information included in marketing material shall be supported by documentation which can be provided on request.

There is, however, no need to provide such documentation concerning information that has been approved in connection with the issue of a marketing autorisation.

4.3 “Important Notice” and Withdrawal of Registration

Information regarding new, serious side effects or contra-indications, limitations on indications and decisions to withdraw the medicinal product from the market because of side-effects, shall be sent out separately to prescribers and chemists. The designation “Important Notice” shall only be used when sending out information of this kind. When in the public’s interest, notification of the withdrawal of a medicinal product shall always be sent to prescribers and chemists. The reasons for such withdrawals shall be stated.

4.4 The Norwegian Pharmaceutical Product Compendium (“Felleskatalogen”)

Felleskatalogen AS publishes “The Norwegian Pharmaceutical Product Compendium of Medicinal Products marketed in Norway” in separate editions for human and veterinary medicine. All medicinal products marketed by the members of the Norwegian Association of Pharmaceutical Manufacturers shall be included in the Norwegian Pharmaceutical Product Compendium.

4.5 Documentation and disclosure in agreements and income

All agreements concerning interaction between the pharmaceutical industry and the individual doctors or groups of doctors shall be made available for public access. Documents containing personal information or trade secrets are exceptions to this rule.

The pharmaceutical company must ensure transparency concerning agreements between the company and medical expertise. Medical personnel giving lectures at courses, seminars etc. should not make reference to medicinal products without providing information about any association or collaboration that they might have with or financial support from a pharmaceutical company.

4.6 Disguised promotion
Request for appointments with health professionals must never be presented in such a way that the real intent is disguised.

5. DISGUISED MARKETING MATERIAL
Marketing material shall not be presented in such a way that its real objective is disguised.
Promotion must not be disguised as market research.
Information material sponsored or produced with financial support from the industry must be labelled with the sponsor’s company name.

6. PROMOTION IN HOSPITALS
6.1 The pharmaceutical companies’ obligation to acquire information
All pharmaceutical companies involved in marketing activities towards separate health enterprises have an obligation to in advance acquire information about prevailing rules.

6.2 Demand for prearranged appointments with health enterprises
Meetings between company representatives and the health enterprise’s employees must be agreed in advance. Unannounced visits shall not take place.

6.3 Fees and gifts
Health enterprise employees and employee representatives can not on behalf of themselves or others accept gifts, provisions, services or other benefits which could influence, or are likely to influence actions, preparation of cases or decision-making in an improper manner.
This does not, however, apply to inexpensive gifts such as promotional material, flowers etc., provided these are not covered by the previous paragraph. Decisions concerning this topic shall be based on Regulation relating to healthcare personnel’s access to receive gifts, provisions, services and other benefits, 2005, § 3.
Gifts do not only include material objects, but also other benefits such as personal discounts on products and services.
Payment to hospital employees for assignments such as advisory board, lectures, consultancy etc. must be approved by the health enterprise.
The hospital employee is responsible for obtaining the approval.

6.4 Courses, congresses, professional meetings etc.
Invitations to employees concerning courses, congresses, professional meetings etc. must be addressed to the health enterprise. The invitation must always contain information about the identity of the organiser and sponsor of an activity.
Hospital employees can participate at such events if approval from the health enterprise is obtained. The hospital employee is responsible for obtaining the approval.
The health enterprise should keep track of and be able to document all approved activities.
Travel expenses in professional contexts are generally covered by the individual health enterprise. Approval from the health enterprise must exist in cases where travel expenses are covered by others. This rule does not apply for short distance travels, where joint transportation is the most practical arrangement.
6.5 Support for courses, congresses, professional meetings etc organised by the health enterprise.

Courses, congresses, professional meetings etc organised by the health enterprise should be arranged without financial or practical support from pharmaceutical companies.

6.6 Training for patients and relatives

Agreements on training for patient and relatives can be entered into, e.g. support for preparing patient brochures or education and training through learning centres or other initiatives. Only healthcare personnel and patient representatives can be in charge of the direct contact with patients and relatives.

7. GIFTS, COVERAGE OF EXPENSES AND THE USE OF HEALTH PROFESSIONALS AS CONSULTANTS

7.1 Regulation on gifts and services

a) Gifts shall not be given to doctors or other health personnel, except when the gift is of insignificant value, for the time being NOK 100.-, and is directly related to a medical or pharmaceutical practice. Such items shall only contain the name of the product, the generic name of the components, and the name of the marketing agent.

b) Professional gifts shall have a value that does not exceed NOK 1000. One such item can be distributed to each doctor per year.

c) No financial benefits should be offered to doctors or Health Personnel. Support to bodies of the Medical Association or groups of doctors may only be agreed in the form of buying advertising space, payment for renting exhibition space or enclosing promotion material. General support to the NMA such as financial support for the running of the body, associate memberships or non-specific benefits is not accepted.

d) Financial support to cover travel and accommodation costs in connection with professional events can be provided in accordance with article 7.2 of the Rules governing Drug Information.

e) The industry may contribute grants/scholarships alone or in cooperation with the Medical Association. The donors must not be represented on the board or have any influence in deciding who will receive the grant/scholarship.

f) Financial or practical support for the running of medical offices etc. is not acceptable.

g) When pharmaceutical firms purchase services from doctors, the payment must be commensurate with the service. No fees may be paid for services for which public reimbursement is available or for which payment is made in some other manner. The payment of fees and other remuneration shall take place in accordance with good accounting practice.

h) Payment is not allowed in order to get access to the health professionals' time. This does not preclude using health professionals as consultants as stated in section 7.3.

i) No rent shall be paid for meeting rooms in medical offices.

j) Donations to institutions or organisations, with the limitations stated in 7.1.c, are only allowed if they are made for the purpose of supporting healthcare or research, they are documented and kept on record by the donor/grantor; and they do not constitute an
inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. Support for the participation of health professionals at scientific meetings are covered in section 7.2.

k) Contracts between industry and institutions or organisations under which the institution or organisation provide any type of services to companies are only allowed if they are made for the purpose of supporting healthcare or research, and the contract does not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

7.2 Events organised or sponsored by the Pharmaceutical Industry

a) The pharmaceutical firm can cover expenses in connection with events aimed at health personnel only if the purpose of the event is to provide professional updating of the participants. The event must be of a modest standard, and financial support shall not exceed the rates in the Norwegian Government Travel Allowance Scale. All events must be planned so that unnecessary travel or accommodation costs are avoided. Hospitality must not exceed what healthcare professional recipients would normally be prepared to pay for themselves.

b) Congress fees can be paid by the pharmaceutical firm. Pharmaceutical firms may only provide financial support for attendance at professionally recognised events within the therapeutic areas in which the company is engaged in research and development or offers medicinal products.

At events to which the pharmaceutical industry contributes, the professional programme and participation by the individual doctor must amount to at least 5 hours per day with the exception of the day of travelling, for which the requirement is 3 hours of professional programme unless the travel itinerary makes this impossible. Evening meetings must have at least 2 x 45 min. of professional programme.

Events, courses etc. which contribute approved CME accreditation points for doctors shall be arranged without financial or practical contributions from pharmaceutical companies.

c) Pharmaceutical companies may not direct invitations to events towards health professionals who may not receive promotion for prescription only medicines, even if the event in question does not include promotion for prescription only medicines. This does not however, preclude separate meetings with information about non prescription (OTC) medicines. Such meetings may be held at the working premises of the health professionals. Following submission of an application, the secretariat for the Committee for Drug Information may approve exceptions from the above if there is a reasonable scientific rationale behind such an event.

d) The pharmaceutical company may cover travel expenses for round-trip travel by the main means of transport and for connecting travel. The pharmaceutical company may also pay accommodation and meals. Meals may also be provided outside the hotel and paid for by the pharmaceutical company if this seems appropriate. Alcoholic beverages shall not be served, except beer and wine with meals.

e) In case of travel the event must have a real professional connection to the travel destination. Events should be held at venues that are appropriate and convenient to achieve the professional purpose of the event. Sponsorship may not be granted by a pharmaceutical company if the venue is associated with sporting or leisure activities or is considered renowned or extravagant.
Pharmaceutical companies may not provide financial support for attendance at such events if the destination causes the event to be clearly associated with something else than its professional content.

The combined Norwegian participation at events abroad shall account for a reasonable proportion of the total participation at the event.

f) Prior approval must be obtained from the Committee for Drug Information for events abroad. This also applies to events in connection with clinical trials.

The programme etc. for other events with contributions from the pharmaceutical industry shall be submitted to the Committee for Drug Information in advance.

g) Non-professional activities are not to be paid for by the pharmaceutical company, neither directly nor indirectly. The above, however, is no impediment for health personnel themselves to fully pay the costs of non-professional activities in connection with the professional event.

h) When attending events sponsored by the Pharmaceutical Industry, the participant can not be accompanied by their spouse/companion.

i) In case of travel paid by a pharmaceutical company, the ticket should not be used for holiday/leisure purposes.

j) The pharmaceutical company is obliged to ensure that health personnel are informed about their duty to procure permission from their employer.

k) The pharmaceutical company, in its invitation to the event, has a duty to specify which costs are covered in connection with the event and not to cover any additional costs. The company also has a duty to refer to the LMI’s and the Norwegian Medical Association’s standard information on events organised by the Pharmaceutical Industry.

l) The pharmaceutical company is obliged to keep records of it’s activities. The records must contain the complete professional and non-professional programme, as well as a specification of what activities are paid for by the firm. The records must be in accordance with the outlines prepared by the Committee for drug information. This information must be kept by the company for a period of two years after the event took place. The Committee may demand access to the records.

7.3 The use of health professionals as consultants

It is permitted to use healthcare professionals as consultants and advisors, whether in groups or individually, for services such as speaking at and chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or travel. The arrangements that cover these genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfill all the following criteria:

a) A written contract or agreement is agreed in advance of the commencement of the services which specifies the nature of the services to be provided and, subject to clause (g) below, the basis for payment of those services;

b) A legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
c) The criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;

d) The number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified need;

e) The contracting company maintains records concerning, and makes appropriate use of, the services provided by consultants;

f) The hiring of the healthcare professional to provide the relevant service is not an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product; and

g) The compensation for the services is reasonable and reflects the fair market value of the services provided. In this regard, token consultancy arrangements should not be used to justify compensating healthcare professionals.

In their written contracts with consultants, companies are strongly encouraged to include provisions regarding the obligation of the consultant to declare that he/she is a consultant to the company whenever he/she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company. Similarly, companies that employ, on a part-time basis, healthcare professionals that are still practising their profession are strongly encouraged to ensure that such persons have an obligation to declare his/her employment arrangement with the company whenever he/she writes or speaks in public about a matter that is the subject of the employment or any other issue relating to that company.

Limited market research, such as one-off phone interviews or mail/e-mail/internet questionnaires are excluded from the scope of this code, provided that the healthcare professional is not consulted in a recurring manner (either with respect to the frequency of calls generally or of calls relating to the same research) and that the remuneration is minimal.

If a healthcare professional attends an event (an international event or otherwise) in a consultant or advisory capacity the relevant provisions of modesty in section 7.2. will apply.

8. PERSONS EMPLOYED IN PHARMACEUTICAL INDUSTRY

8.1 Pharmaceutical company representatives

a) Pharmaceutical company representatives shall be given adequate training by or on behalf of the company in which they are employed, and they shall have the professional expertise required to enable them to provide information about the company’s products in an exact and responsible way.

b) They shall perform their tasks ethically and responsibly.

c) They shall conduct their activities in conformity with the Rules governing Drug Information.

d) In all meetings, in accordance with public legislation, pharmaceutical company representatives shall ensure that those visited are provided with the product descriptions for all the products presented, or that such information is made available to them.
e) They shall immediately provide their company with any information they receive concerning the use of products which they have presented, and in particular information relating to side effects.

f) Pharmaceutical company representatives shall be registered with the Norwegian Association of Pharmaceutical Manufacturer’s Training Board in accordance with regulations pertaining thereto.

8.2 Other employees

a) All employees who are in any way involved in the preparation or approval of promotional material or information directed at doctors or other health personnel shall be fully acquainted with the provisions of the Rules governing Drug Information.

b) All companies shall establish a scientific service to deal with information about the company’s products. The scientific service shall comprise a doctor or a pharmacist who shall be responsible for approving all marketing material before it is published. In the case of veterinary products, approval shall be given by a veterinarian or a pharmacist.

9. MEDICINAL PRODUCT SAMPLES

In accordance with public regulations, a limited number of free samples of a particular medicinal product may be supplied to healthcare professionals who are qualified to prescribe that medicinal product in order to familiarise them with the product; but only in response to a written request, signed and dated, from the recipient.

Only one of the smallest packages can be distributed to each doctor per year. The package must be marked with “Free medicinal product sample – not for sale”. Samples of medicines in the categories A and B can not be distributed. Receivers of free medicinal product samples must be registered and the lists kept for a minimum of two years.

10. RESPONSIBILITY

10.1 Scope of responsibility

The responsibility for pharmaceutical information applies to information as a whole, both in form and content.

10.2 Responsible parties

The responsibility for ensuring compliance with the Rules governing Drug Information rests with the Norwegian company in question, while responsibility for foreign companies rests with the authorised Norwegian representative. Authorised Norwegian representatives are also responsible when the information function is managed by the foreign company.

11. SUPERVISION

The medicinal product information provided by the industry is subject to continual evaluation and guidance by the Committee for drug information. The members of the Norwegian Association of Pharmaceutical Manufacturers have a duty to provide the Secretariat with all information and promotional material used in marketing.