LMI

LEGEMIDDELINDUSTRIEN

The Association of the Pharmaceutical Industry in Norway

# *RULES FOR MARKETING OF MEDICINAL PRODUCTS*

Established by the Association of the Pharmaceutical Industry in Norway's (LMI) Annual General Meeting of 15 November 1994 with subsequent amendments at the Annual General Meetings of LMI on 31 March 2009, 3 March 2010, 14 March 2011, 23 November 2011, 20 November 2013 and most recently at the Annual General Meeting on 14 November 2014.

## *Introduction*

The main responsibility of the pharmaceutical industry is to develop new and effective medicinal products, to improve existing medicinal products, and to disseminate information about them such that they benefit the individual patient.

In addition to other marketing activities, the industry should therefore organise professional meetings and contribute to the continuous raising of the level of competency in the public health service. Such arrangements shall be characterised by a high professional content, and otherwise be of a modest standard. The marketing of medicinal products shall be carried out in accordance with the rules in this document.

All members of the Association of the Pharmaceutical Industry in Norway (LMI) have a duty to comply with the Rules for Marketing of Medicinal Products as laid down by LMI. All pharmaceutical companies have a duty to provide healthcare professionals with relevant, reliable and adequate information about the medicinal products they are marketing.

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 to which LMI is affiliated. The latest version of EFPIA's Code of Practice on the Promotion of Medicines was adopted by EFPIA on 5 October 2007 with entry into force at national level 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. Besides the Rules for Marketing of Medicinal Products, LMI's rules consist of agreements between LMI and the Norwegian Medical Association (NMA), the regional health enterprises, the Norwegian Nurses' Organisation (NSF), the Norwegian Association of Pharmacists (NFF) and the Norwegian Federation of Organisations of Disabled People (FFO), as well as guidelines adopted by LMI's Board. Reference is also made to public law rules and regulations.

The Association of the Pharmaceutical Industry in Norway and the Norwegian Medical Association have jointly established the Committee for Information on Medicinal Products,

which acts as a voluntary self-regulating supervisory body for all members of both associations. The Committee's functions include ensuring that the Rules for Marketing of Medicinal Products are observed.

In the event of doubt about the interpretation of the rules, conclusive weight shall be attached to the manner in which similar matters have been resolved or practised under the prevailing Council Directive and under the Code of Practice on the Promotion of Medicines as laid down by EFPIA.

## *Scope of rules*

The rules apply to all forms of marketing. This means any information or sales promotion activity carried out by or on behalf of a pharmaceutical manufacturer that is designed to influence the prescribing, marketing, sale and consumption of the company's medicinal products.

The Rules apply to all forms of communication between manufacturers/suppliers and healthcare professionals or the general public. The Rules apply to all forms of marketing, including advertising in professional journals and direct marketing, the activities of pharmaceutical company representatives, the use of audio-visual systems such as films, video recordings, database services and the like, and the distribution of product samples and 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.

## *The Rules do not apply to:*

Labelling and package leaflets or summary of product characteristics (SPC) that are approved in connection with the issue of a marketing authorisation.

The correspondence, possibly combined with other material of a non-marketing nature, needed to respond to specific questions about a specific medicinal product.

Specific and informative announcements concerning new packaging, warnings of possible side effects, product catalogues and price lists, etc., 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 medicinal products.

Clinical trials, including non-intervention trials, do not lie within the scope of the Rules. Pharmaceutical companies must nonetheless meet the requirements regarding the publishing of information about clinical trials; see "Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases" and "Joint Position on the Publication of Clinical Trial Results in the Scientific Literature".

## *The individual rules*

## *1. Marketing authorisation and price*

### 1.01 Time when marketing takes place

A medicinal product must not be marketed before a marketing authorisation and approved price have been issued. Marketing without an approved indication is not permitted.

### 1.02 Approved summary of product characteristics (SPC)

Marketing must be consistent with the information provided in the approved summary of product characteristics, and currently applicable reimbursement rules.

## *2. Contents of promotional material*

### 2.01 Public laws and regulations

Marketing must be in compliance with public laws and regulations. All promotional material must contain clear:

a) Key information pursuant to Section 13-7 of the Medicinal Products Regulation. The information shall be consistent with an approved summary of product characteristics and be dated.

b) Prescription status of the product

c) Where relevant, the retail price and conditions for reimbursement

### 2.02 Reminders

Compliance with the provisions of 2.1 above is not required if the advertisement is only intended to serve as a reminder, provided that it contains only the name of the product, the generic name of the active component(s), and the name of the marketing agent.

## *3. Requirements regarding promotional material*

### 3.01 Balanced information

Promotional material for medicinal products shall be accurate, balanced, truthful and objective, and sufficient to enable the recipient to form an opinion about the therapeutic value of the product in question. The promotional material should be based on the most recent evaluation of scientific material possible, and should clearly reflect this material. It must not distort the facts, place unjustified emphasis, commit omissions or in any other way provide misleading information.

### 3.02 Documentation requirements

All information included in promotional material shall be supported by documentation that can be provided on request. However, there is no need to provide such documentation

concerning information that has been approved in connection with the issue of a marketing authorisation.

### 3.03 Correct use of medicinal products

Advertisements for pharmaceutical products must promote correct use of the product by presenting products in a balanced manner without exaggerating properties or value. An advertisement must not imply that a product has particular properties or value without providing documentation to support the assertions.

### 3.04 References

Quotations from medical and scientific literature must be faithfully reproduced and precise references provided as to the sources.

### 3.05 Comparative advertising

Comparative advertising must not be misleading and must be based on comparable and relevant product characteristics. Both the manufacturer's own and competitors' products must be presented in a balanced, fair and objective manner.

### 3.06 Illustrations

All illustrations used in advertising should clearly indicate the precise source(s). Where illustrations have been modified, this shall be clearly stated. Illustrations must not present a misleading picture of the characteristics or value of the product.

### 3.07 Safe

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

### 3.08 New

The word "new" must not be used more than one year after a product or indication has been introduced.

### 3.09 Side effects

It must not be claimed that a product has no side effects or risk of creating dependency.

### 3.10 "Important Notice" and Withdrawal of Registration

Information regarding new, serious side effects or contraindications, 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 pharmacies. The designation "Important Notice" shall only be used when sending out information of this kind. Notification of the withdrawal of a medicinal product shall always be sent to prescribers and pharmacies when it is in the public interest. The reasons for all such withdrawals shall be stated.

### 3.11 The 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 Association of the Pharmaceutical Industry in Norway shall be included in the Compendium.

### 3.12 Meetings with healthcare professionals

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

## *4. Use of quotations*

### 4.01 Quotations

Quotations from medical and scientific articles shall be accurate and reflect the findings and conclusions of the articles. References shall always be given for quotations.

## *5. Marketing shall be of a high ethical standard*

### 5.01 High ethical standard

Pharmaceutical manufacturers shall maintain a high ethical standard in their marketing at all times. Marketing of medicinal products shall:

a) Never be such as to discredit or undermine confidence in the pharmaceutical industry.

b) Always be such that account is taken of the special nature of medicinal products, and the position of the prescriber.

Advertisements for medicinal products shall not be offensive.

### 5.02 Transparency

Pharmaceutical firms shall ensure that there is transparency concerning activities and agreements entered into with healthcare professionals or groups thereof. Medical personnel should not refer publicly to the company's medicinal products without at the same time disclosing that they have assignments or similar for the industry.

## *6. Distribution of promotional material*

### 6.01 Parties to whom promotion may be directed

Promotion shall only be directed at those who can reasonably be assumed to have an interest in the information.

### 6.02 Address lists and registration

Address lists shall be kept up to date. The industry is obliged to remove healthcare professionals who request it from their lists. All registration of personal data on healthcare professionals must be in accordance with prevailing rules.

### 6.03 Telefax and e-mail

The use of telefax, e-mail, text messages or other forms of electronic communication for promotion purposes is conditional on the recipient having accepted or requested it, in accordance with current legislation.

## *7. Marketing transparency*

### 7.01 Disguised promotion

Promotional material shall not be designed in such a way as to disguise its real objective.

Requests for appointments with healthcare professionals must never be presented in such a way as to disguise their real intent.

Market surveys must not be disguised promotion.

### 7.02 Studies as disguised promotion

Clinical trials, non-interventional studies and other types of studies for determining the efficacy and side effects of medicinal products in clinical use shall not be disguised promotion.

### 7.03 Promotional and editorial material

When a firm pays for or in some other way arranges for publication of promotion material in the media, such material shall not be designed in such a way that it can be interpreted as being independent editorial copy.

### 7.04 The names of sponsors shall appear

Information material sponsored by or produced with financial support from the industry shall bear the sponsor's name.

## *8. Do not provide personal advice on medical treatment*

Should members of the public request personal advice on medical treatment, the company shall recommend contacting the public health service.

## *9. Events arranged or sponsored by the pharmaceutical industry*

### 9.01 The primary purpose of all arrangements shall be continuing professional development.

All meetings arranged by or sponsored by the industry, such as promotion meetings, scientific meetings, conferences, symposia or other meetings (including, but not limited to advisory boards, professional excursions or meetings in connection with planning or conducting of clinical trials and non-intervention trials) must be held at a place that is appropriate to the primary purpose of the meeting. Hospitality must only be provided when appropriate, and should then be in conformity with the other Rules for Marketing of Medicinal Products.

### 9.02 Requirements relating to travel outside Norway

Pharmaceutical firms must not arrange or sponsor arrangements located outside Norway unless:

a. The arrangement has been approved in advance by the Committee Secretariat, and
b. The majority of those invited are from countries other than Norway, and the destination appears reasonable given the departure point of the attendees or
c. The location of arranger or expertise makes it more reasonable to hold the arrangement outside Norway.

It is not permitted to sponsor or pay for healthcare personnel to travel to or attend arrangements abroad held by third parties. Nor is it permitted to contribute to travel to which the prohibition in the first sentence applies, through direct or indirect support, practical assistance, travel scholarships, general financial support to employers or in any other manner. However, this paragraph does not prevent employees in the pharmaceutical industry from inviting healthcare professionals to summing up meetings/meetings devoted to specific topics at international congresses.

### 9.03 International congresses

Norwegian rules and regulations shall apply to international congresses and meetings held in Norway.

### 9.04 Cost coverage

Hospitality in connection with arrangements shall be limited to travel, meals and overnight accommodation. Any necessary attendance fees may also be paid.

All types of hospitality offered to healthcare professionals shall be of a reasonable scope and level, and shall be a necessary premise for the professional programme. As a general rule, it shall not exceed what healthcare professionals would have paid if they were to pay it themselves. The following also apply:

a. For dinner and lunch, the rates which are currently established by LMI's Board of Directors shall not be exceeded. These rates are established for dinner at 70 % of the State's representation rates (currently NOK 822) and for lunch at 40 % of the State's representation rates (currently NOK 172) for meals at medical offices.

b. For events outside Norway, the established maximum amount in the event's host country shall prevail.

c. Alcoholic beverages shall not be served, apart from beer and wine with meals.

d. There shall be at least 5 hours per day of professional programme. On travel days there shall be three hours of programme insofar as this is feasible.

e. Arrangements may not be made for tickets to be used wholly or partly for holiday purposes.

f. The company is obliged to specify what costs are covered.

g. Companies shall maintain records of their activities. The records shall contain the complete professional and non-professional programme, as well as a specification of what activities are covered. The records must be set up in conformity with a form prepared by the Committee for Information on Medicinal Products. 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.

See also section 13, third paragraph concerning rules for advance approval of expense coverage or sponsorship associated with arrangements held by healthcare professionals.

### 9.05 Accompanying persons prohibited

Only persons who are qualified to attend may be invited. Accompanying persons are not permitted.

### 9.06 Social activities and prohibition of certain destinations

Hospitality shall never include sponsorship or organisation of entertainment or social activities. Companies shall avoid destinations that are associated with sports or leisure activities or that are known to be extravagant.

### 9.07 Definitions

”Reasonable”: All hospitality shall be reasonable. By reasonable is meant that payment shall not be made for more expensive hospitality, meals or travel than is strictly necessary to achieving the professional purpose of the trip and/or arrangement.

”Appropriate”: All locations that are used for the industry’s arrangements shall be suitable for the purpose of the meeting on the basis of both professional and logistical criteria. The choice of location shall not be offensive or provide grounds for a conclusion that the purpose of the meeting is anything other than strictly professional.

”Extravagant”: Places that are particularly exclusive, such as restaurants, tourist destinations or other places that are known to be particularly exclusive, shall not be used by the industry.

”Associated with”:  For example, skiing destinations are normally associated more with sporting than with professional activities, and shall therefore not be used.

## *10. Information and educational material, and medical utilities for healthcare professionals*

No gifts or financial benefits shall be given, offered or promised to healthcare professionals, with the exceptions listed below. The rules in this chapter do not apply to trial packages.

Information and educational material may be distributed to healthcare professionals providing that the material is of limited value, is directly relevant to the occupation of the recipient, and is of direct benefit in the treatment of patients.

Medical utilities may be distributed for the purpose of promoting the education of healthcare professionals and for treatment of patients, providing that they are of low value, have a bearing on the recipient's profession, and are not a part of the recipient's usual professional activity, such as consumables and other products that are necessary for the performance of the healthcare professional's occupation.

By "low value" is meant a maximum amount to be fixed by LMI's Board.

Information and educational material and medical utilities may not be offered or distributed as an inducement to recommend, prescribe, purchase, give, sell or administer a medicinal product.

The rules in this chapter do not apply to information material or medical utilities that are a part of the risk management plan for the medicinal product.

## *11. Donations to the public health service or research*

Given the restrictions in point 10.4, donations to institutions or organisations are only allowed if the purpose is to support medical research or treatment. Documentation concerning the donation is to be kept by the company. The donation must not involve the recommendation, prescription, purchase, delivery, sale or administration of a particular medicinal product. Financial support to individuals is not permitted. Financial support to allow healthcare professionals to attend professional arrangements is covered by section 13. Companies may publish information to the effect that donations have been made.

## *12. Services provided by institutions and healthcare professional organisations*

Contracts between the industry and an institution or an organisation of healthcare professionals which entail the institution or organisation providing a service for the industry are only allowed if they are made for the purpose of supporting medical research or treatment and the contract does not entail recommending, prescribing, purchasing, supplying, selling or administering a specific medicinal product.

## *13. Financial support for healthcare professionals*

Financial support for healthcare professionals, or associations of healthcare professionals, may only be provided in accordance with currently applicable laws and regulations, section 9 of the Rules for Marketing of Medicinal Products and cooperative agreements between LMI and regional health enterprises, the Norwegian Medical Association, the Norwegian Association of Pharmacists, the Norwegian Nurses' Organisation and the Norwegian Federation of Organisations of Disabled People.

Payment may not be made in order to gain access to healthcare professionals' time. This does not preclude the use of healthcare professionals as consultants as stated in section 14.

Expenses for arrangements, or sponsorship of arrangements held by healthcare professionals shall only be covered in the case of arrangements with a concept that is approved in advance by the Committee Secretariat.

## *14. The use of healthcare professionals as consultants*

### 14.01 Requirements regarding the use of consultants

Healthcare professionals may be used as consultants and advisors, either individually or in groups, for services such as speaking at and chairing meetings, participating in clinical and other scientific studies, training a company's own personnel, being on advisory boards and participating in market research where such participation involves remuneration. Assignments and consulting services must, to the extent relevant in the individual case, fulfil all the following criteria:

a) A written contract or agreement must be made in advance, in which the assignment/ service to be provided and the conditions for payment of compensation are described in detail (see g) below).

b) A legitimate need for the services must have been identified prior to requesting the service and entering into an agreement.

c) The criteria for selecting consultants must be directly related to the identified need and the persons responsible for selecting the consultants must have the expertise necessary to evaluate whether the healthcare professionals in question meet those criteria;

d) The number of healthcare professionals engaged for the assignment/service must be reasonable in terms of meeting the identified needs.

e) The pharmaceutical company shall maintain records of agreements and contracts made with healthcare professionals. The results of the services provided/assignments carried out shall be used only in accordance with the contract/agreement that has been made.

f) The engagement of healthcare professionals to carry out assignments/provide services shall not be an inducement to recommend, prescribe, purchase, sell or administer a specific medicinal product.

g) The compensation paid shall be reasonable and represent a fair market value for the assignment carried out/service provided.

### 14.02 Written contract or agreement

Pharmaceutical companies are urged strongly to include in their written contracts with healthcare professionals concerning assignments/provision of services a requirement that the consultant declares that he/she is a consultant for the company whenever he/she writes or speaks in public on a topic that is the subject of the agreement or otherwise relates to the company in question. Similarly, companies that employ, on a part-time basis, healthcare professionals who also practise their profession elsewhere are urged strongly to ensure that such persons mention their employment with the company whenever they express themselves publicly about matters relating to their employment relationship or to the company generally.

### 14.03 Market surveys

Limited market surveys, such as one-off phone interviews or e-mail/internet questionnaires are excluded from the scope of these provisions, provided that the healthcare professionals are not consulted regularly (either in terms of a number of surveys or to respond to the individual survey) and that the remuneration for participation is minimal.

### 14.04 Level of cost coverage for consultants

If a healthcare professional attends an event (international or otherwise) in a consulting or advisory capacity, the requirements regarding moderation in section 9.6 will apply.

## *15. Transparency regarding transfer of value from pharmaceutical companies to healthcare professionals or healthcare organisations*

### 15.01 Reference to EFPIA's regulations and the scope of application of the rules

All members of LMI shall disclose direct or indirect transfers of value to healthcare professionals or healthcare organisations, in accordance with the rules in this section. In cases of doubt or a need for further details, see EFPIA's Disclosure Code.

A prerequisite for the rules on whether publication can occur is that the activity is not affected by prohibitions in Norwegian law or the industry's own regulations, including rules which prohit transfer of value in connection with travel or conference participation. In particular, this refers to "conference resolutions" (Rules 9.02, second paragraph), rules on "concept approval"(9.02, first paragraph a) and rules for/agreements with the regional health authorities.

Transfers of value that concern only over-the-counter medicines, take place within the framework of ordinary sale of medicinal products, or refer to veterinary products, are not subject to the rules in this section. Nor does the duty of disclosure apply to the value of free samples of medicinal products, meals in a professional context at approved rates or ordinary information and marketing costs.

Definitions according to this section:

- According to this section, a healthcare organisation is any legal person who provides healthcare assistance or patient treatment, such as health authorities, medical offices etc.
- By healthcare professionals is meant persons defined in Section 13-7 of the Medicinal Products Regulation or in the Health Personnel Act, and others who work in health organisations with healthcare assistance or patient treatment.
- By transfer of value is meant any direct or indirect transfer of a benefit with a financial value.
- Research and development: transfer of value to recipients related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice), (ii) clinical trials (as defined in Directive 2001/20EC), or (iii) non-interventional studies which involve the collection of patient data from health personnel or on their behalf (as mentioned in section 15.01 in EFPIA HCP Code)

### 15.02 Annual reporting and form of disclosure

Reporting of transfers of value shall take place for one calendar year at a time. The first year for which a report must be submitted is 2015. Reporting shall take place within 6 months of the end of the reporting period. The report must remain in the public domain for at least 3 years from the time when the information is made available. Reporting shall take place on the company's website. The companies undertake to make it possible for LMI to create a link to a joint reporting website. The transfers of value shall be reported in Norwegian but the pharmaceutical companies are encouraged to report in English as well. The information must be maintained for at least 5 years after the reporting period has expired.

### 15.03 National and international reporting

The reporting shall be in line with the national regulations in the country in which the recipient has their primary workplace or their primary accommodations. If the recipient has his place of operation in a European country other than Norway, and the company is unable to report the transfer of value through the parent company abroad, the company shall report the transfer of value in accordance with Norwegian regulations.

### 15.04 Individual and aggregate disclosure

Disclosure in connection with transfer to a healthcare organisation shall take place at individual level in the following cases:

a) Donations and grants

b) Contribution to costs related to Events, coverage of participation fees and travel fees shall be listed as separate items on an individual basis (indirect support).

c) Fees for Service and Consultancy which are not covered by the rules on aggregated reporting. Fees for assignments and coverage of fees shall be listed as two separate amounts in the form.

For Transfers of Value to health personnel, reporting at an individual level shall occur in the following cases:

a) Contribution to costs related to events where the company pays for travel and accomodations.
b) Transfers of value for Service and Consultancy which are not covered by the provisions on aggregated reporting. Fees for assignments and coverage of fees shall be listed as two separate amounts in the form.
c) Coverage of participation fees.

For health personnel, it follows from the Norwegian Personal Data Act that consent must be obtained from recipients before individual reporting can take place. If consent does not occur, the transfer of value shall be reported aggregated. For health personnel and health organisations, it is a prerequisite for individual reporting that there not be any legal impediment to publication on an individual level.

Aggregated information shall be specified in number and percentage of the total number of recipients and the aggregated amount which is not listed individually shall be specified.

When transfers of value are made indirectly to health personnel, it shall only be specified once.

Transfers of value must be clearly related to research and development, see the definition in 15.01, in order for reporting to be able to take place on an aggregated level. Costs connected to the activity are recognised in the same way.

The pharmaceutical companies shall publish a note summarising the methodologies used to specify the disclosures and the identification of Transfers of Value. This summary shall include the accrual of payments extending over a longer time then the period of publication, VAT and other legal tax information, exchange rate differences and other information, which could affect the size of the amounts. All reporting shall occur on EFPIA's standard forms.

## *16. Non-intervention studies*

Reference is made to separate guidelines adopted by LMI for non-intervention studies.

## *17. Samples of medicinal products*

### 17.01 Parties who can accept samples of medicinal products

In accordance with public regulations, a limited number of free samples of a particular medicinal product may be distributed to persons who are qualified to prescribe medicinal products in order to familiarise them with the product; but only in response to a written request, signed and dated, from the recipient. Samples of medicinal products must not be

distributed for the purpose of achieving a recommendation, prescription, purchase, delivery, sale or administration of a particular medicinal product.

### 17.02 Documentation requirements

Lists shall be kept of those who have received free samples of medicinal products. The lists shall be kept for at least two years.

### 17.03 Quantity restrictions

Only one sample of the smallest size may be distributed per doctor per year. Samples of medicinal products may not be distributed for more than two years after a product has been introduced onto the Norwegian market.

A new medicine, in this connection, is a medicinal product that has acquired marketing authorisation (MA) or a new indication. The extension of the MA to cover higher strengths or dosage forms for existing indications or for other package sizes (number of units in the package) cannot be regarded as new medicines.

### 17.04 Labelling requirements

The package shall be labelled ”Free sample of medicinal product – not for sale”.

### 17.05 Restrictions regarding prescription status

Samples of medicinal products in categories A and B may not be distributed.

## *18. Pharmaceutical company employees*

### 18.01 Pharmaceutical company representatives

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 accurate and responsible way.

a) They shall act in compliance with LMI’s Rules for Information on Medicinal Products and public laws and regulations.

b) They shall perform their tasks ethically and responsibly.

c) In accordance with public legislation, pharmaceutical company representatives shall ensure at all meetings that those visited are provided with the SPCs of all products presented, or that such information is available to them.

d) They shall immediately provide their company with any information they might receive concerning the use of the product they are presenting and, in particular, information relating to side effects.

e) Pharmaceutical company representatives shall be registered with the Association of the Pharmaceutical Industry in Norway's Training Board in accordance with regulations.

f) In their contact with healthcare professionals, pharmaceutical company representatives must never consciously conceal their identity or that of the company they are representing.

### 18.02 Other employees

All employees who are in any way involved in the preparation or approval of promotional material or information directed at doctors or other healthcare professionals shall be fully acquainted with the provisions of the Rules for Information on Medicinal Products.

All companies shall establish a scientific service to deal with information about the company's products. This scientific service shall appoint a promotion or compliance officer who shall be responsible for approving all marketing material before it is published. The person concerned must be a doctor, pharmacist or person with similar qualifications who has been approved on application to LMI. In the case of veterinary products, approval shall be given by a veterinarian or a pharmacist.

## *19. Responsibility, compliance and monitoring*

### 19.01 Scope of responsibility

Responsibility for marketing applies to information as a whole, both form and content.

### 19.02 Responsible parties

The responsibility for ensuring compliance with these Rules for Information on Medicinal Products 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.

### 19.03 Monitoring

The medicinal product information provided by the industry is subject to continual evaluation and guidance by the NMA's and LMI's joint Committee for Information on Medicinal Products. 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. The members undertake to abide by the Committee's decisions.

For case processing and sanctions in the event of breach of these rules, please see the statutes of the NMA's and LMI's joint Committee for Information on Medicinal Products.