The Association of the Pharmaceutical Industry

2024

GUIDELINES FROM THE COMMITTEE'S SECRETARIAT

HUMAN MEDICINAL PRODUCTS

THE NORWEGIAN VERSION SHALL ALWAYS PREVAIL IN CASE OF ANY DISCREPANCY OR INCONSISTENCY BETWEEN THE NORWEGIAN VERSION AND ITS ENGLISH TRANSLATION.

THIS EDITION OF THE INDUSTRY RULES OF THE ASSOCIATION OF THE PHARMACEUTICAL INDUSTRY IN NORWAY (LMI) HAS BEEN ADOPTED AT LMI'S ANNUAL GENERAL MEETING ON APRIL 23rd 2024 AND CAME INTO FORCE ON MAY 1st 2024

In the period from May 1st 2024 to August 1st 2024, no material or activities shall be considered in breach of the rules if they breach only those provisions which were new in this edition of the Rules.

Preamble

The pharmaceutical industry in Norway bases its activities on knowledge, professionalism, openness, and integrity for the benefit of patients. Our main tasks are to develop new and effective medicinal products, improve existing treatment regimens, and make these available and known in such a way that they benefit the individual patient.

The pharmaceutical industry possesses a great deal of knowledge about medicines and disease awareness. By informing and sharing our knowledge, we contribute to the correct use of medicines and thus to better health. We are concerned that the right patient receives the right medicine at the right time. To achieve this, it is essential that the person making decisions about the patient's treatment has access to as good information as possible and knows all possible treatment options - both for medicinal and non-medicinal treatments.

The public sector finances the bulk of medicinal product purchases in Norway. Through their choices, especially in clinical activities, doctors manage large sums on behalf of society. This places significant demands on the interaction between doctors, other healthcare professionals and the pharmaceutical industry. Detailed legislation and requirements for transparency, which govern and limit how our member companies can interact with the outside world, contribute to increased trust between society and the pharmaceutical industry. We want to help create an environment where decision makers, patients and society consider the pharmaceutical industry as a credible and trustworthy partner; where respect, integrity, openness, and the patient first, are at the centre.

We, the people in the pharmaceutical industry, work diligently to research and develop new, innovative medical treatments and products to meet today's, as well as tomorrow's, treatment needs. We are proud of what we achieve; every day we help to improve and save lives.

THE RULES

LMI's industry rules (**the Rules**) is the Pharmaceutical Industry in Norway's own set of regulations.

These rules regulate pharmaceutical companies' advertising for medicinal products, information about medicinal products, health and disease, and the industry's interaction with health professionals and patient and user organisations.

These rules are based on the set of regulations of the European Federation of Pharmaceutical Industries and Associations (EFPIA), the representative body of the pharmaceutical industry in Europe, to which LMI is affiliated. The rules have been drawn up in compliance with the Medicinal Products Act of April 12, 1992 no 132 (**Medicinal Products Act**), the regulation regarding medicinal products of December 18, 2009 no. 1839 (**Medicinal Products Regulation**) and European Parliament and Council Directive 2001/83 EC (**Medicinal Products Directive**) and GDPR. Otherwise, we refer to the applicable laws and regulations, including the Marketing Act, valid at any given time.

The rules for interaction (part VI and VII) are also based on agreements between LMI and The Norwegian Medical Association (NMA), the regional health enterprises, the Norwegian Nurses' Association (NNA), Norwegian Association of Pharmacists (NFF) and Norwegian Federation of Organizations of Disabled People (FFO).

PURPOSE

The purpose of these Rules is to establish a complete, updated and accessible set of regulations that facilitate good, quality-assured and regulation-compliant information and interaction with Healthcare Professionals, Healthcare Organisations, Patient- User Organisations and Patient-User Organisations Representatives.

DOCUMENT'S STRUCTURE

This document is divided into seven main parts with a total of 27 chapters.

For some of the rules, there is a guideline from the Committee's secretariat detailing

how the rules are to be interpreted. A small triangle next to a rule indicates that there will be guidance for that rule. The guidelines are printed in a different font and background at the end of the relevant chapter. Gradually as the rules are updated, more guidelines will be incorporated into them.

CHANGES

The rules are adopted by LMI's annual general meeting that is normally held each year in March. A new, updated edition of the Rules will normally apply from April 1 of every year.

The Board of LMI has the authority to make changes to the rules between general meetings if necessary.
Guidelines are prepared by the Committee's secretariat and are usually updated annually along with a new edition of the Rules.

CONTACT

If you have any questions related to the Rules, the Committee's secretariat may be contacted by e-mail, telephone or post:

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CHAPTER 1. DEFINITIONS

Unless otherwise specified, the following definitions apply in these Rules:

1.1 Advisory Board: Advisory Board means a group of experts chosen by a Member Company consisting of external consultants with special expertise within the relevant technical field and offers advice on - and insight into - scientific or health-related issues.

1.2 Destination and location: Destination refers to a geographic location, i.e., a city or town.

Location refers to a venue, such as a hotel, restaurant, or event location where dining etc. occurs.

1.3 Digitalis: Digitalis is the name of the intranet accessible by the Member Companies of LMI (The Association of the Pharmaceutical Industry in Norway).

1.4 Healthcare Organizations: Healthcare organizations are defined as any legal entity, (i) which provides health assistance or patient treatment, such as a health enterprise, doctor's practice etc. (ii) which is a research or institution within medical, biological or other health-related disciplines such as a university or another institution of learning, (iii) through which health professionals provide health services.

1.5 Healthcare Professionals: Healthcare Professionals means doctors, dentists, authorized nurses, pharmacists, opticians and dental hygienists as well students in the related subjects.

1.6 Other Healthcare Professionals: Other Health Professionals means Healthcare Professionals according to the Health Professionals Act § 3, who are not covered by the definition in 1.5.

1.7 Healthcare Professional Association: Healthcare Professional Association means a non-commercial legal entity consisting of Healthcare Professionals or Other Healthcare Professionals having a common interest, subject or discipline they wish to promote.

Healthcare Professional Associations must follow the rules for Health Organizations unless otherwise stated.

1.8 Medicinal Products: A medicinal product is defined as any substance, drug or preparation that is either claimed to be or is suitable for the prevention, cure or alleviation of disease, disease symptoms or pain, or affects physiological functions or which may be applied or given to restore, modify or affect physiological functions through a pharmacological, immunological or metabolic effect, or to detect disease.

1.9 Pharmaceutical samples
A pharmaceutical sample is the smallest pharmaceutical package available for distribution to healthcare professionals according to chapter 22. The purpose of such distribution is to ensure that health-care professionals can familiarize them-selves with the product.

1.10 Member Company: A Member Company is defined as (i) any enterprises that are members of LMI, (ii) EFPIA's Member Companies which in respect of EFPIA's regulations are obliged to comply with local regulations in Norway, and (iii) other enterprises which through agreements have agreed to comply with these Rules.

1.11 Patient Organization: Patient Organization means a non-commercial interest organization for disabled and chronically ill persons and/or their families and other interested members of the general public.

1.12 The Rules: By the Rules means this document encompassing LMI's rules for the sector. The guidance is presented in a different font at the end of the respective chapter.

1.13 Advertising of Medicinal Product: By the term advertising of pharmaceutical products, means any form of outreach/ pro-active informational activities, campaigns, influencing and other measures intended to promote the prescribing, providing, sales or use of pharmaceutical products.

1.14 Patient Organization Representative: A person, who has the mandate to represent and communicate messages and views on a particular illness-related matter, on behalf of a Patient Organization.

1.15 SmPC: SmPC means Summary of Product Characteristics which are Preparatomtale approved by the Norwegian Medicines Agency as part of the marketing authorization for a Medicinal Product. The SmPC forms the basis of knowledge for Healthcare Professionals in their application of a Medicinal Product. SmPC information is updated throughout a Medicinal Products life cycle as and when new data becomes available. The SmPC is the only form of summary characteristic of product sanctioned by the Norwegian authorities.

CHAPTER 1 DEFINITIONS

Subsection 1.4 Healthcare
The requirement for a Healthcare Organization to be a "legal entity" means that it must have an organization number. Examples are Health Trust, a private hospital/clinic, a pharmacy, or the Faculty of Medicine at the University of Oslo. A pharmacy chain is not considered a Health Trust.

Subsection 1.5 Healthcare
There are various definitions of the term healthcare professional existing in the Norwegian legislation. The definition, in subsection 1.5 used in these Rules, is taken from Section 13.1 of the Norwegian Regulations relating to Medicinal Products (legemiddelforskriften).

The definition of HCPs that can be exposed to prescription drugs advertising was extended July 1 st 2020, and now includes opticians and dental hygienists. This complies with the Regulations regarding requisition of medicines.

The definition in subsection 1.5 also includes Healthcare Professionals who are not necessarily in clinical practice, but who have the relevant authorization/ license to prescribe or administer Medicinal Products, such as retired or unemployed doctors or pharmacists.

Subsection 1.6 Other Healthcare Professionals
In Norway, a large group is considered healthcare professionals. In addition to doctors, nurses, pharmacists, etc. considers the Health Personnel Act of 2 July 1999 no. 64 (the «Healthcare Professional Act») pharmacy technicians, health secretaries, radiographers, clinical nutritionists, physiotherapists, bioengineers, mv. as healthcare professionals.

Hence, the Healthcare Professional Act has a broader definition of healthcare Professional than the chapter on drug advertising in the Medicines Regulations.

By Other Health Professional means Healthcare Professional according to the Health Personnel Act §3 which are not covered by the Medicines Regulations § 13-1 (Healthcare Professional according to the industry rules).

Section 13-9 of the Medicines Regulations allows more professional groups, which fall under "Other

*Healthcare Professional", to participate in **interdisciplinary** advertising meetings. This requires participation by Healthcare Professionals in accordance with the Medicines Regulations § 13-1 and that the employer considers participation **professionally necessary.***

Subsection 1.7 Healthcare Professionals Association
Examples of a Healthcare Professionals Association include the Norwegian Neurological Association, the Norwegian Society of Cardiology, various professional groups under the Norwegian Nurses Organization.

The Healthcare Professional Associations are subjects to the same provisions as Healthcare Organizations with regard to, for example, provisions on support in Chapter 17, provisions on the purchase of services in Chapter 18 and the like.

Subsection 1.9 Medical samples
NOMA has prepared a guideline for the distribution of free samples, among other things, wholesale certification is required, cf. the Regulations relating to wholesale permits.

Subsection 1.13 Advertising of Medicinal Products
When deciding what to consider as "designed in the purpose to promote the sales or the use of" includes – in addition to the messaging/mentioning itself and its design, the context in which the messaging is conveyed and its recipients.

Furthermore, the judgment will depend on who initiates the action, and the severity of the action itself. Such as, whether information is directed towards healthcare professionals (push), or whether healthcare professionals are seeking out the invitation (pull).

Examples of what is included under the term "Promotional material". This list is not exhaustive:

- *Promotional materials in journals and those sent by direct mail or e-mail*
- *Pop-up advertisement, that appears in web browser, typically labelled "advert", when it is* ordered or purchased by a *Member Company. So called "teasers" or "ad-plugs."*
- *Advertising brochures*
- *Member Companies sales activities, including all electronic and printed material used by them*
- *Distribution of medical samples*
- *Content marketing*
- *Promotional materials or stands at meetings.*
- *All other sales activities regardless of the format – for example, audio-visual recordings, broadcasting, internet, social media etc.*

Examples of what is not included under the term "Promotional material". This list is not exhaustive:

- *Labelling, package inserts or SmPCs approved by the issue of a marketing authorization*
- *Factual information of a technical nature relating to price, packaging, pack size, for example, where this is not connected to area of application or an SmPC*
- *Technical instructions for use provided that it only reproduces the package leaflet.*
- *A Member Company's statements in relation to disease awareness.*
- *Press releases (see Chapter 9)*
- *Non-interventional trials (see Chapter 21)*
- *Clinical trials, including informative material necessary for the implementation of a clinical trial (protocol, Investigator's brochure, patient consent etc.).*

See Regulation no. 1321 of 30 October 2009 relating to the clinical testing of Medicinal Products for human use.

- *Training material and Risk Management Plans which constitute preconditions for a marketing authorization (see The Norwegian Medicines Agency guidelines)*
- *Instructions for the technical administration of a Medicinal Product formulated in accordance with the Norwegian Medicines Agency guidelines.*
- *General company profiling e.g., mention of the Member Company's revenues, number of employees, or the Member Company's research work on condition that no mention is made of registered or potential products with a view to promoting sales or use.*

Specifically concerning tenders, contact with the authorities and other buyers Tenders and negotiations with relevant personnel (buyers, decision-makers) at purchasing organizations, for example, health authorities, the Norwegian Institute of Public Health (Folkehelseinstituttet) or the Norwegian Hospitals Procurement Service (Sykehusinnkjøp HF/Hospital Procurement HF, previously known as HINAS/LIS) are not considered Promotional materials. Tenders submitted in advance of receiving "Positive Opinion"/marketing authorization must contain information/reservations pertaining to these.

A Member Company may have contact with decision-makers within the pharmaceutical field such as the authorities, managers in Healthcare Organizations, parties in the tender process, buyers in pharmacies, politicians etc. without such contacts being regarded as Promotional materials, on the condition that contact intended to assist with the formulation of framework conditions for Medicinal Products, financing etc. conforms to current practice in Norway (Market Access activities), and that Market Access activities are formulated according to the following criteria:

a) The number of participants contacted must be kept to a minimum and not exceed the number necessary for fulfilling the purpose of the contact.
b) The material used must be clearly marked with the name of the sender/company, and appear otherwise neutral in design (i.e., must not be product-branded)
c) All information must be plain, factual and objective, and must not appear promotional Information must be based principally on facts in the form of financial information, technical information, information from authorized SmPCs or package inserts or data from scientific publications.

The information must be of plain design and not carry marketing claims.

Proactive distribution or dissemination of information about one or more Medicinal Products to Healthcare Professionals or other groups which falls outside the scope of Market Access Activities is not included under this exemption.

<u>Answers to specific enquiries</u>
Correspondence, possibly including any plainly designed material of a nonmarketing nature, that is needed for answering specific, unsolicited questions from an HCP about a particular Medicinal Product is not regarded as "Advertising".

For a question to qualify as "unapproached", another Member Company must never invite or encourage such questions. In the process of judging whether conveying of such relevant information is permitted, the Member Company employee's role and title might be of relevance.

It is recommended that employees responsible for conveying or treating such information, is in the medical department, or in other non-commercial roles, of the Member Company.

The conveying of information to several healthcare professionals, such as a department, when participating at a nonspecific event as an invited guest speaker to present non-approved products or indications, might be considered Advertisement, following a specific review. Should the information request be specified to a specific issue and, if the group receiving the information is limited to those considered particularly interested (smaller groups) within this area, the action of conveying might not be considered Advertisement and will be accepted.

<u>Pharmaceutical development/pipeline Specifics</u>
Proactively mentioning of scientific studies and data related to a pharmaceutical pre-launch, might be prohibited, due to point 4.1, stating that advertisement for products without a Marketing Authorization is prohibited.

Medical or scientific information exchange related to pharmaceuticals, can however not be considered advertisement, and therefore legitimate. Upon such decision, it is imperative whether the specific information is conveyed to promote the sale of the product. It needs to be individually reviewed whether, or not, the conveying of information was conducted to promote sales of a/the product.

Originally, it will be considered proactive mentioning of a pharmaceutical development when:

1. *The product development has reached the stage where a Marketing Authorization has been submitted (either nationally/EMA/FDA etc.), or*
2. *Introduction of product to market is imminent (less than one calendar year is considered imminent) or if a Member Company has published a phase III study or if a Member Company is familiar with the results of the phase III study and has temporary analysis' available)*
3. *Information about potentially new indications for an already*
4. *approved pharmaceutical is provided.*

Recent developments show that the FDA and EMA allow "filing" (application for MT) based on phase II data. This could be important in assessing whether something is considered advertising.

The context in which the information is provided, will be highly relevant when reviewing whether pipeline information is considered Advertisement. Providing information about a company's research, might be considered prohibited due to pre-marketing, when conveying to doctors at a hospital, however, providing the same information to politicians in a debate, when it is obviously not for sales

promoting purposes, might be permitted. The shape and form on the information provided will also be relevant when reviewing the context.

Pipeline information, when crucial to complete an Advisory Board or recreating for clinical trials or establishment of other research collaboration, will, typically, not be considered Advertisement.

Conveying of pipeline information is not considered Advertisement, when provided by a third party at scientific event or congress where the Member Company is merely a sponsor and not a (co) host? Such information, when provided at symposiums or by a Member Company on a stand, however, needs to be reviewed towards these guidelines.

Other practical questions connected to the timing of product marketing
The practical question is raised of the degree to which the planning of future marketing is permissible if marketing authorization is expected to be forthcoming in, for example, six months' time. It is normally permitted to send meeting invitations where the recipient is asked to set aside some time to hear about a "new product" assumed to be of interest to the party concerned. It is however not permitted to mention that a new product will be brought along, to mention the area of indication or to give any information on the product in any way. Such letters must, therefore, be sent from the Member Company in general.

CHAPTER 2. SCOPE OF THE RULES

2.1 Human Medicines

The Rules apply for Advertising and activity connected with Medicinal Products for human consumption.

The Rules apply to Advertising and activities connected to both non-prescription Medicinal Products – including Medicinal Products in packages exempt from medicinal prescription – and prescription- only Medicinal Products as defined by the context.

2.2 To whom do the Rules apply?

The Rules apply to all Member Companies and their interactions with Healthcare Professionals, Other Healthcare Professionals, Healthcare Organizations, Healthcare Professional Organizations, Patient Organizations and Patient Representatives in Norway.

Unless otherwise stated, this applies also outside of Norway when Member Companies address the above-mentioned groups.

Additionally, the rules apply to Member Company's interaction with any official or employee of a government agency or other organization (whether in the public or private sector), that may prescribe, purchase, supply, recommend or administer Medicinal Product.

This applies unless others stated.

For foreign companies with authorization in Norway, the authorized representative in Norway is responsible for compliance with the Rules. The responsibility of the authorized representative in Norway also applies when information/interaction is administered/managed by a department outside Norway.

2.3 Platforms upon which the Rules are practiced

The Rules are applying regardless of

platform format; printed, stated, electronic or digital communication.

2.4 Breach of the Rules and sanctions

LMI and the Norwegian Medical Association (Den norske legeforeningen) have set up the Committee for Information on Medicinal Products ("The Committee"), which is a self- regulating supervisory body for all Member Companies and members of the Norwegian Medical Association.

The Committee is the addressee for any allegations of breach of these Rules. Case handling and sanctions pertaining to any breach are referred to the Committee's bylaws.

CHAPTER 2 SCOPE

Subsection 2.1 Human Medicines
For activities relating to Medicinal products for animals, view Industry Rules regarding marketing of veterinary medicinal products.

Delimitation against other Member Company activities
If a Member Company markets Medicinal products for human consumption as well as other products which do not come under these Rules – for example, health products or dietary supplements – these Rules will apply only to the company's human medicines business. This means that the company must follow these Rules for all Advertising and all activities partly or wholly connected to the company's human medicines business. This presupposes that the Member Company makes a clear distinction between the product areas in its business. If the Member Company does not make a clear distinction between the product areas in its business, the Rules will be exercised across the whole business.

For example: A Member Company markets a Medicinal Product for pain relief. The company also has other pain- related products in its portfolio which are not Medicinal Products. The restrictions within these Rules do not apply to the company's marketing of non-Medicinal Products; for example, the prohibition on gifts in Chapter 11 or amount restrictions in Chapter 16 do not apply. This presupposes however that the Member Company makes a clear distinction between the product areas in its business. This means, for example, that the two product categories may not be marketed together, at the same time or in connection with each other, nor should they appear (by design/color scheme) to be associated.

Subsection 2.2 To whom the rules apply
By Norway means mainland Norway, Jan Mayen, Bjørnøya and Svalbard. Since the Rules apply in Norway, this means that they also apply to information sent to Norway from abroad that is aimed at Norwegian Healthcare Professionals or the public. The language is not crucial, but if information appears in Norwegian, it will generally be considered to be "aimed at" Norwegian citizens.

For foreign companies with authorization in Norway, the authorized representative in Norway is responsible for compliance with the Rules. The responsibility of the authorized representative in Norway also applies when information/interaction is administered/managed by a department outside Norway.

If a foreign Member Company arranges an event in Norway (e.g., an exhibition stand, symposium etc. in connection with an international

congress in Norway), these Rules will apply, and all materials and activities must abide by Norwegian rules.

The rules also apply if a third-party acts on behalf of a Member Company.

CHAPTER 3. HIGH ETHICAL STANDARDS AND TRANSPARENCY

3.1 High ethical standards

The pharmaceutical industry's conduct should always adhere to a high ethical standard.

When processing personal data about an individual's physical or mental health, ethical assessments must be made, and applicable laws and regulations must be followed. All treatment of personal data on Healthcare Professionals should be in accordance with the prevailing regulations on the treatment of personal health data.

Mentioning of Medicinal Product should:

a) Never reduce confidence in the pharmaceutical industry.
b) Always be of a nature such that it takes account of the Medicinal Product's speciality, as well as the recipient's point of view

Advertising of Medicinal Product should not be disrespectful.

Advertising should only be directed towards those who can be reasonably assumed to have an interest in receiving it.

The Member Company should assess the amount and frequency of its communications in relation to the individual recipient.

Address lists should be kept up to date. A Member Company should remove Healthcare Professionals from their lists when requested to do so.

3.2 Prohibition of undue influence

Member Companies must not unduly influence a decision to recommend, prescribe, buy, give, sell or administer a Medicinal Product. This includes all of the Member Company's activities, such as preparation and distribution of materials and aids, financing of third-party events, through catering and support, through engagement of consultants, etc. to carry out assignments and services or through the distribution of medicinal samples.

3.3 Transparency with regard to activities and interactions

Member Companies should ensure transparency regarding activities and agreements entered with Healthcare Organizations, Healthcare Professionals, Other Healthcare Professionals, Healthcare Professional Associations and Patient Organizations, as well as Patient Organizations Representatives.

It must be clear at all times who pays for, or in any way arranges for - or contributes to - its publication/distribution. Such information should not be designed in a way that it could be interpreted as being independently editorial content.

Content that is communicated as supplements or together with newspaper articles or other editorial content must be clearly marked as "PROMOTIONAL MATERIAL", or equivalent.

Advertising material must not be designed to conceal its true purpose.
Clinical trials, non-interventional trials and other types of trials intended to map a Medicinal Product's effect and side effects in clinical use must not be disguised Advertising. Such trials must be carried out for a scientific purpose.

3.4 A Member Company should not give personal advice on medical

treatmentMember Company should not give personal advice on medical treatment. If an enquiry is received from a member of the public concerning personal advice on medical treatment, the Member Company

should advise the person concerned to contact the health service.

3.5 Direct healthcare professional communication (DHCP)

DHPC, in cooperation with the Norwegian Medicine Agency (NMA), sent to healthcare professionals to inform them of important new safety information about a medicine and any actions they should take. The logo "Safety information in cooperation with The Norwegian Medicines Agency", must only be used for this purpose.

3.6 Felleskatalogen

Felleskatalogen AS publishes FK-texts on all medicinal products that are on the Norwegian marked. Member Companies medicinal products must be published on www.felleskatalogen.no

The FK-text must comply with the SmPC at all times.

3.7 Doctors' continuing medical education

The event may not provide CME accreditation in doctors' continuing medical education.

CHAPTER 3 HIGH ETHICAL STANDARDS AND TRANSPARENCY

Subsection 3.2 Prohibition of undue influence

"Undue" means an influence which is suitable to influence Healthcare Professionals in such a way that other assessments than the professional and socio-economic ones are the basis. The ban is intended to shield Healthcare Professionals (and others) from being influenced into official actions they would not otherwise do, and which are likely to lead to unfair discrimination of patients or treatment that is not purely health-related justified. Support in the form of e.g., equipment or Medicinal Products must never bind the future use of Medicinal Products or otherwise link the Healthcare Organization to Member Companies in an inappropriate way.

Subsection 3.3

Transparency with regard to activities and interactions Rules regarding processing of personal data primarily the Personal Data Act) of 15 June 2018 no. 38, including ("GDPR").

The distinction between editorial content and content marketing

Content in an editor-controlled independent publication is not normally considered advertising / marketing. By independent editorial means that the content is not designed, initiated, influenced or financed by an industry representative with an interest in sales of a Medicinal product. A Member Company may however give tips regarding content or interview objects etc. Independent editorial content follows domestic rules applying for the press "Vær Varsom poster". Editorial content, e.g., newspaper article, must be separated from content marketing. Content marketing is, for example, advertising brochures or other types of media where information in favour of certain products, treatment options or a Member Company, is depending upon the Member Company's advertising. Content marketing is considered Advertising when the content contains mentioning of product. Linking to editorial content may in some cases fall under the definition of Advertising if the use / linking is done with the aim of promoting sales. A specific assessment must be made in each case as to whether there is an advertising purpose. If a Member Company has written, ordered, organized and / or financed an article that is published, it must be clear what

relations the article author (s) have with the Member Company and how the financing has been arranged.

Subsection 3.5 DHCP
View the Norwegian Medicines Agency websites for additional information about DHCP.

CHAPTER 4. MARKETING AUTHORISATION

4.1 Timing of product marketing

A Medicinal Product must not be marketed before it has been given a marketing authorization and, in the case of prescription- only Medicinal Products, the approved price has been given.

Product marketing without the approved indication is not permitted.

4.2 Approved SmPC

Advertising must correspond to the information given in the approved SmPC, as well as to the applicable regulations for reimbursement.

It is not permitted to use statements in a Medicinal Product's Advertising which do not agree with information in the SmPC.

It is permitted to use statements not used in the SmPC or which are derived from the SmPC if these statements supplement information in the approved SmPC and where they:

a) confirm or clarify the information

b) are consistent with the SmPC

c) do not misrepresent or distort the information in the approved SmPC

CHAPTER 4 MARKETING AUTHORISATION

Subsection 4.1 Timing of product marketing
It is forbidden to advertise a Medicinal Product before it has received a marketing authorization. In the case of prescription-only Medicinal Products, they must have been given an approved price as well. See guidance point 1.13 about prohibited pre-launch.

Unless NOMA includes conditions for entry into force in the price decision (determination of maximum price), rights and obligations usually come into force at the time of issuance of the decision (decision date). If no reservation has been made as to when the price decision will come into force, and companies start marketing after the decision date without the product being available for sale, it should be made clear from the advertisement that the product is only available for sale after the XX date. This is to avoid the advertisement being misleading.

Requirements relating to pricing decisions on prescription-only Medicinal Products
The reason that a prescription-only Medicinal Product cannot be marketed before it has an approved price is that the pricing information is part of the mandatory information (see subsection 7.2.

Reimbursement decision
It is permissible to market a Medicinal Product while awaiting a reimbursement decision.

Subsection 4.2 Approved SmPC
All Advertising must correspond with approved SmPCs. As a general principle, a conservative interpretation

of the SmPC should form the basis of all Advertising.

Since the SmPC often contains information, which is not absolutely limiting, a discretionary assessment will often form the basis for determining whether the relevant Advertising corresponds to the SmPC.

As a rule, it will be in keeping with the SmPC to relate results from trials described in section 5.1 of the SmPC (pharmacodynamic properties), as well as complementary trials (including clinical practice trials and phase 4 trials, such as non-interventional trials/registered trials) where the primary results/conclusion correspond with the SmPC. The presentation of such complementary trials must be accompanied by clear evidence of the patient population and trial type being presented. Any other information necessary for understanding the results must also be explained.

As a rule, it will not be in keeping with the SmPC to:

- *Present results from trials which have chiefly been carried out upon*
- *a population without an approved indication*
- *Introduce new dosages, strengths or formulations not found in the SmPC*
- *Introduce completely new effect parameters not found in or capable of being derived from the SmPC.*

All presentations of results should be done with reference to scientific work in accordance with the rules in subsection 7.7 below.

CHAPTER 5. DIGITAL CHANNELS, ETC.

5.1 Digital Channels

Digital channels consist of websites, social media, e-mail, apps, podcasts and more.

5.2 Specifically regarding the websites and Webpages

5.2.1 General Information

All websites are targeted at the public unless it is clearly stated that the website is intended exclusively for Healthcare Professionals, through a disclaimer or similar before access is granted.

Websites that contain disease awareness information and that are mainly intended for the general public cannot contain a separate section/website intended for healthcare professionals, links to pages/websites intended for healthcare professionals or links to advertising for medicinal products. It is permitted to link to other websites/webpages for the general public, and to the front page/page for the general public on the company's website.

5.2.2 Prescription-only Medicinal Products

Advertising for prescription-only Medicinal Products is allowed only on websites clearly marked “for Healthcare Professionals only”, or with words to that effect.

Mandatory information for prescription-only Medicinal Products (see subsection 7.2) can be placed in links provided that the links are obvious and easy to see and that they are direct links (one-click).

5.2.3 Non-prescription Medicinal Products

Mandatory information for non-prescription Medicinal Products, cf. Subsection 7,6 must be displayed in the Promotional material itself and cannot be replaced by links to more comprehensive information.

5.2.4 Third-party websites

It should be made clear when a user is leaving a website that is owned, operated or controlled by a Member Company, or

when they are linking to a website that is not owned, operated or controlled by the Member Company.

Member Company must ensure that links to third party websites do not contain advertising of prescription drugs to the public nor illegal advertising towards Healthcare Professionals.

5.3 Digital communication

Digital communications directed towards an individual is as a main rule permitted only if the recipient has previously given their consent to receive them.

5.4 Social media

5.4.1 General information

Social media are websites and apps that facilitates to create and share content, and to participate in social networks.

Member Companies must monitor their channels for comments and input from users and make any necessary changes such as deleting individual posts or comments. Member Companies must also identify possible side-effects and report them in accordance with statutory requirements.

The Member Company must make clear the terms and conditions that apply to comments and sharing, and that messages and comments posted will be monitored.

The Member Company must fulfill its responsibility for reporting side effects.

5.4.2 Personal use of social media

Member Company's employees use of social media related to the Member Company or itsproducts, are covered by the Rules.

CHAPTER 5. DIGITAL CHANNELS, ETC.

Subsection 5.2.1 General information

The Rules applying to the internet make the distinction between websites and webpages. A website is a domain – for example www.pharmceuticalcompanyname.no, www.theme.no – and a web page is a page on a website.

It is recommended that there be a clear division (preferably in the form of tabs) between pages for the public and those for Healthcare Professionals.

The website should clearly show the cross-over from pages designed for public to those meant for Healthcare Professionals only.

Delimitation should be done in the form of a "pop up" or other clear marking that the content is reserved for healthcare professionals, through words such as HCP's "only" or other suitable synonyms.

Digital front page

Digital front pages are digital reminders that lead to additional content such as ad plugs or banner ads.

These are used to click on digital supplements / e-magazines / advertising.

When using digital front pages, the purpose of the content must be clearly stated. In content marketing, the digital front page should be clearly marked with, for example, "advertisement, advertiser content etc.

The digital front page should be accurate, balanced, truthful, objective, not misleading and should promote the article / content in a way that makes one understand what the article is going to be about and who is behind the front page.

When the digital front page leads to

advertising for a prescription drug, it should clearly state "for healthcare professionals only".

It is not permitted to link from a page meant for the public to a website for a Medicinal Product e.g., from www. diseaseawarenessinformation.no to www.product.no

In addition, the following are relevant for prescription drug reminder ads and ad plugs:

1. *Digital reminder advertisements may contain only the elements set out in clause 7.3.*
2. *Ad plugins cannot by themselves be promotional. The plug should not contain identifying statements such as "tender winner", "first choice", "now approved by Decision Forum" or have recognizable characteristics of the product. Other digital advertising is considered full digital advertising and must meet the requirement for mandatory information.*

Text in the search results *(website address and the brief description of the website), when designed by the Member Company, must follow the Rules for advertising.*

Subsection 5.2.2 Prescription Medicinal Products

When communicating with Healthcare Professionals, mandatory information may be communicated in a document that is available to all HCPs watching / participating, or by being included directly in the audio-visual communication itself. In that case, it must be clear how this information is made available.

Advertising must always be balanced regarding its use and risk.

The safety information must be given such space or emphasis that the reader in a simple way perceives it and the advertising message. The safety information is placed in relevant sections, based on a specific assessment of each website / page layout, so that the relevant message appears balanced. In addition, it should be easy for the reader to obtain the safety information in the relevant layout, for example in an overview menu.

Mandatory information or a link to mandatory information should be placed in a way that the user does not have to search for it, as well as appear as part of the information on the main page / section of menu selections.

Subsection 5.2.3 Advertising for nonprescription Medicinal Products

Advertising must always be balanced with regard to its use and risk. This applies at all levels (visual fields/links). Unbalanced Advertising in one visual field may not be compensated for by linking to another page with more comprehensive information.

With regard to mandatory information, cf. Subsection 6.6, in Advertising of nonprescription Medicinal Products on the Internet, the following guidelines apply:

- *Advertising films for nonprescription Medicinal Products may be shared on the Internet, including publication on, for example, the company's website or YouTube channel, and/or communicated through other channels (such as Facebook or Instagram). Mandatory information must appear in a clear and legible manner in the film itself. Because films on the Internet and other digital channels are often played without sound, it is recommended that the mandatory text be displayed during the full running time of the film. Otherwise, refer to the general guidelines for TV Advertising set out in Subsection 6.8.*

- *Advertising for non-prescription Medicinal Products in the form of static text or images published on the Internet must be designed such that all information, including the mandatory information, is legible and visible, irrespective of whether it is displayed on a computer, a smart- phone or a tablet. In the case of dynamic Promotional materials including rotating images, it is recommended that the mandatory information remain permanently displayed throughout the Promotional material. This will help ensure that the user can read the safety rules and will allow the company to have the rest of the Promotional material in motion or displaying changing images/text if desirable. Mandatory information must in all circumstances be displayed clearly (sufficiently large font / good contrast / on screen long enough).*

For advertisement on smartphones, tablets etc., meaning digital channels with limited field of view, the following design is recommended:

1. *The advertisement must include the name of the Medicinal Product, as well as the names of the active substance(s) in accordance with point 6.6 a.*
2. *Information that is essential to ensure correct administration of the product, including important precautions and usage, is highlighted in a green field, with a white cross and a circle with the following text: "non-prescriptive Medicinal Product," according to point 6.6 b.*

The green field should:

- *Consist of the entire width of the advertisement and minimum 1/5 of the total advertisement.*
- *Adapt the amount of information to make it legible.*
- *As a minimum, contain the most important information to ensure correct usage. Particularly relevant information can be who not to take the product (considering the person's age, health condition, particular groups, such as pregnant/ breast feeding etc.), as well as information about indication and the products target group.*
- *Contain an area marking that you can get additional information, which can be linked, or provide the option to scroll for further information.*

3. *The advertisement needs to contain the text: advising the user to "carefully read the packaging and leaflet," in accordance with point 6.6 c.*

The advertisement and the expanding information need to appear coherent.

What considers mandatory information might vary. A specific decision must be made each time.

Subsection 5.2.6 Third-party websites
If a Member Company links to information about the Member Company's Medicines on a third-party website, the linking itself may be considered to have the purpose of promoting sales. A specific assessment must be made in each individual case, including the website to which it is linked and the purpose of the linking.

Subsection 5.3 Digital communication
Regarding consent view the Marketing Act (lov-2009-01-2) § 15 following, and GDPR implemented to Norwegian law (Lov-2018—06-15-38).

The rules on content, formal requirements, access restrictions, etc. applies regardless of the platform used, be it website / page, blog, podcast, app, etc.

In general, as elsewhere, wherever a company has influence, the company has a responsibility, also when using an external third party. Third party liability means that a third party cannot go further in its statements on behalf of the Member Company than the company itself can do.

A Podcasts that contain advertisements for prescription drugs must be made available to healthcare professionals only.

Blogs, available to the public, should only be used to promote disease awareness information. This due to the Medicines Regulations §13-6 f, "advertising of medicines to the general public must not contain material that refers to recommendations from researchers, healthcare professionals, or persons who are neither researchers nor healthcare professionals, but by the virtue of their reputation can promote the use of a drug".

Subsection 5.4.1. General information
In this context, "social media" is taken to mean, for example, Facebook, Twitter, YouTube, Instagram and LinkedIn.

The Member Company's "page" also includes the company's area, account or channel.

If there is an option to set up closed groups/pages with access control, and if such pages are reserved for Healthcare Professionals, it is permitted to advertise prescription-only Medicinal Products on these pages.

Targeted Advertisement for prescriptiononly Medicinal Products is permitted and can be communized through social media, provided the platform clearly defines Healthcare Professionals as the target group based on unbiased and credible criteria (related to recipient's education, profession, position etc.), and that the advertisement is explicitly available for the defined target group. Such advertisement should be marked "for healthcare professionals only."

Subsection 5.4.2. Personal use of social media
It does not take much for comments, shares or "likes" of content to be considered representative of the Member Company's position.

In cases where such activity/sharing is considered Advertising, the Rules must be followed.

This means that a good deal of information will not be suitable for employees of Member Companies to share/like/comment on in social media.

Member Companies should prepare internal guidelines for their employees regarding how they are to behave in social media – both on their private profiles/pages and those of the Member Company that employs them.

The Member Company's employees are permitted to participate in social debates and may also take part in discussions that include information about diseases awareness.

CHAPTER 6. ADVERTISING AIMED AT THE PUBLIC

6.1 General requirements

Promotional materials for Medicinal Products should be plain and factual. They should promote sensible use. Promotional materials must not give a misleading or exaggerated image of a Medicinal Product's properties and medicinal value.

It needs to appear clearly that the product is a Medicinal Product.

Promotional materials must not lead to use of the Medicinal Product that is not medically justified.

6.2 Promotional materials for Medicinal Products aimed at the public are only permitted for non-prescription Medicinal Products

Promotional materials for Medicinal Products aimed at the public are only permitted for non-prescription Medicinal Products or Medicinal Products in nonprescription packaging, and only when they are recommended for diseases or symptoms that do not ordinarily require examination or treatment by a doctor or dentist.

6.3 Prohibited advertising

Promotional materials aimed at the public are not permitted for prescription Medicinal Products or for Medicinal Products that contain substances that are classified in accordance with international conventions on psychotropic and narcotic substances.

This ban does not apply to prescription vaccines for human consumption included in vaccination campaigns launched by the industry and which are authorized by the government.

6.4 Mention of serious disease is not permitted

Promotional materials aimed at the public are not permitted to mention serious diseases such as e.g., tuberculosis, sexually transmitted diseases, cancer or other tumor diseases, chronic insomnia, diabetes or other metabolic disorders.

6.5 Prohibition on promotional gifts, free samples etc.

The inclusion of Promotional materials for Medicinal Products in Medicinal Product packaging in addition to approved package inserts is not permitted. Promotional materials may not be associated with articles, gifts, prizes or any other form of reward.

The issue of free medical samples to the public is not permitted.

6.6 Mandatory information in Advertising aimed at the public

The following information should always be included in Promotional materials aimed at the public:

a) the name of the Medicinal Product together with the name of the active ingredients (generic names)
b) information necessary for the correct use of the Medicinal Product, including area of application and important precautions/warnings
c) a recommendation to the user to carefully read the packaging and package insert.

6.7 Prohibitions applying to Advertising aimed at the public

Promotional materials aimed at the public must not:

a) give the impression that consultation with and treatment by a doctor or other Healthcare Professionals is unnecessary, or undergo surgical procedures, by offering a diagnosis or recommend treatment by correspondence,
b) imply that the effects of the medicine are guaranteed, that it is without side effects or is better than or as good as other treatment or other medicine,
c) imply that a person's health can be improved by taking the medicine,
d) suggest that a person's health may be affected by not taking the medicine, except for vaccination campaigns, point 6.3 second paragraph,
e) is exclusively or mainly aimed at children,
f) refers to recommendations from researchers, healthcare personnel, or persons who are neither researchers nor healthcare personnel, but by virtue of their

reputation can promote the use of a medicinal product,

g) suggests that the medicinal product is equated with a food, cosmetic or other commercial product,
h) suggests that the safety of the medicine or its effect is due to it being natural,
i) a description or a detailed presentation of a case of illness may lead people to make incorrect diagnoses themselves,
j) refers in an exaggerated, intimidating or misleading manner to claims of healing;
k) in an exaggerated, frightening or misleading way uses visual representations of changes in the human body, which are caused by disease or injury, or of the effect of a drug on the human body or parts of it.

6.8 TV Advertising

TV Advertising for Medicinal Products is only permitted for non-prescription Medicinal Products.

CHAPTER 6 ADVERTISING AIMED AT THE PUBLIC

Subsection 6.1 General requirements
When health and disease information, is combined with product referencing, the advertising rules for all information applies.

Labelling of advertising
According to § 2 of the Marketing Act, advertising images and commercials in which the shape, size or skin of a body has been changed by retouching or other manipulation must be marked using a public, standardized mark.

There are requirements for the size of the mark, where it should be placed, etc. For additional information, see the Danish Norwegian Supervisory Authority.no

Subsection 6.6 Mandatory information for Advertising aimed at the public
No reference is required for mandatory information.

b) information necessary for the correct use of the Medicinal Product, including area of application and important precautions/warnings
It is important for Advertising to appear balanced.

This requirement means, amongst other things, that information necessary for the correct use of the Medicinal Product, including areas of application and important precautions/warnings, should be given space and visibility in Promotional materials.

Such information could, for example, include text such as "should not be given to children under the age of three" and "visit your doctor if the complaint does not improve within one week", etc. Other examples could be instructions that the Medicinal Product should not be used by persons with a reduced specific function or who have or have had a specific condition or disease.

It is the target group the advertisement is aimed at that is decisive for how mandatory information must be designed. Content of mandatory information for

over-the-counter medicines will therefore vary:

1. *In the case of advertising for over-the-counter medicines to Healthcare Professionals- mandatory information must be formulated in accordance with 7.2*
2. *In the case of advertising for overthe-counter medicines to Other Healthcare Professionals in interdisciplinary meetings - mandatory information is formulated in accordance with 7.2*
3. *When advertising over-the-counter medicines to Other Healthcare Professionals and other professional groups that are not Healthcare Professionals or Other Healthcare Professionals (not interdisciplinary meetings) - mandatory information is formulated in accordance with Chapter 6.*
4. *When advertising over-the-counter medicines to the general public - mandatory information is formulated in accordance with Chapter 6.*

Mandatory information on prescription drugs, please view chapter 7.

Section 6.7 b Comparative advertising of OTC-products is prohibited.
Statements such as «Norway's best-selling drug», «No. 1 drug» and similar qualifies.

Subsection 6.8 TV Advertising
TV Advertising is only permitted for nonprescription Medicinal Products. However, it is permitted to purchase advertising time for information that is not for advertising of Medicinal Product – e.g., information about diseases awareness or general company profiling.

Design of TV Advertising for nonprescription Medicinal Products

TV Advertising must satisfy the general requirements for Advertising aimed at the public.

Information must be communicated in a clear manner. Particular challenges associated with the format (sound/image) do not change this requirement. It is not sufficient to refer to other information sources (e.g., websites).

TV Advertising normally gives the recipient a short time to grasp the information provided, so particular emphasis should be placed on the following factors:

- *The information contained in Advertising must be easy to take in and understand*
- *All mandatory information must be communicated in a clear manner (refer to the point about precautions below)*
- *The Advertising must be balanced with respect to the product's use and risks.*

The requirement for the Advertising to avoid giving a misleading or exaggerated picture of the Medicinal Product's qualities and medicinal effect means that the Advertising must not, for example, normalize medicinal use as part of an active lifestyle or show exaggerated and immediate effects ("before and after" images).

Length and size of precautions
The precautions must be legible.

Precautions should be presented in one of two ways:

1. *As text during the entire length of the film. The text must be sufficiently large so that it can actually be read. It must be wellcontrasted against the background. The text needs to be*

presented for a sufficiently long time allowing for the entire text to be read.

2. *Shown as a notice at the end of the film, in which case there should be a voice-over and the notice should be displayed for as long as it takes to read the text and for a minimum of five seconds. The text must be sufficiently large so as to be legible and the notice must cover the whole screen.*

Films must not present an exaggerated picture of the preparation's properties or effect.

Films that show patients who experience an exaggerated effect from the product must not be shown. An exaggerated effect, for instance, would be the visualization of an unreasonably rapid improvement of the condition. Nor should exaggerated symptoms of disease which disappear or improve due to the ingestion or use of the Medicinal Product concerned be shown.

An example of a misleading visualization could be a patient worn out by pain subsequently able to carry out strenuous physical activity as a result of the Medicinal Product.

An example of an acceptable visualization of effect could be a film showing an individual in a normal situation of doing housework, or together with children, where self-administered pain treatment is adequate.

Balanced
Advertising may only refer to those conditions covered by the Medicinal Product's indication. The film must not show patients who could be interpreted as having conditions other than those for which the Medicinal Product is actually approved.

Non-prescription Medicinal Product is approved only for use in conditions which are suitable for self-treatment. Advertising for non-prescription Medicinal Products must, therefore, focus only on conditions which can be self-treated. This must be reflected in the film.

An assessment must be made to ensure that all important precautions have been included. In some cases, it will be necessary to indicate, for example, whichpatient groups should not use the Medicinal Product.

Separate sponsorship rules
"Sponsorship" refers to short "billboard" advertisements which are broadcast together with TV programs.

Broadcasting legislation includes separate rules for sponsorship. Fundamentally, the law only allows short texts. In the case of Medicinal Products, special rules take precedence over broadcasting legislation, which means in practice that it is a legal requirement to include the precautions.

The precautions must be legible.

CHAPTER 7. ADVERTISING AIMED AT HEALTHCARE PROFESSIONALS

7.1 General requirements

Prescription Medicinal Products may only be marketed to Healthcare Professionals.

Promotional materials for Medicinal Products should be plain, factual balanced, objective and complete enough

that the recipient can make up his own mind of the therapeutic value of the pharmaceutical. They should promote sensible use in accordance with current prescription regulations.

Promotional materials must not give a misleading or exaggerated image of a Medicinal Product's properties and therapeutic value.

Advertising should be based on the most recent evaluation of scientific material possible and clearly reflect this material. It must not distort, unjustly emphasize or omit findings or in any other way mislead.

It must not be claimed that the Medicinal Product has no side effects or carries no risk of addiction.

Promotional materials must not lead to use of the Medicinal Product that is not medically justified.

Promotional materials should be dated with date of issuance or last revised.

7.2 Mandatory information

Advertisement must comply with public laws and regulations. The advertisement must contain:

a) relevant information that is complete and that corresponds with the summary of product characteristics approved by the Norwegian Medicines Agency,
b) the dispensing provision of the medicinal product,
c) price, and
d) information on pre-approved reimbursement.

The advertisement may alternatively be promoted as a reminder advertisement (reminder) and must then only contain the name of the medicinal product, active substance and the name of the marketer.

7.3 Reminder advertisements

The requirements in the second paragraph of subsection 7.2 need not be followed if the Advertisement is intended solely as a reminder, provided that the Advertisement contains nothing more than the pharmaceuticals name, generic name and name of the marketer.

7.4 Safe

The word "safe", or words to that effect, must never be used without proper qualification.

7.5 News

The word "new" must not be used to describe any Medicinal Product or presentation that has been available, or any therapeutic indication, which has been promoted, for more than one year.

7.6 Documentation requirements

The content of Promotional materials must be verifiable.

All documentation of a Medicinal Product's properties and effects must refer to the product's SmPC or a valid scientific reference (cf. subsection 7.7). References are not required for mandatory information that is included in the ad or technical facts (e.g., marketing authorization, pack sizes, strengths or formulations).

7.7 References

Valid references in Advertising are the SmPC or scientific work that is accessible to the recipient of the Advertising.

Scientific work must, if used as reference, be peer reviewed and published.

When referring to scientific work, including reference to visual representations, quotations, tables and illustrations from these, clear references must be given to where they can be obtained.

7.8 Visual representations, quotations, tables and illustrations

When use of visual representations, quotations, tables and illustrations in Advertising obtained or based on scientific works, these must be reproduced loyally with an accurate source.

If the illustrations have been modified, this

should be made apparent.
Illustrations in form of images, or other visual tools that the company uses in Advertising, must not give a misleading picture of the drug's ability, or value, or in any other way mislead or draw upon exaggerated effects.

7.9 Comparative Advertising

Comparative Advertising must not be misleading and must be based on comparable and relevant properties of products. Both the advertiser's own and the competitor's preparations must be presented in a balanced, fair and objective manner.

7.10 Specifically regarding the Advertising of non-prescription Medicinal Products to Healthcare Professionals

The Advertising of non-prescription Medicinal Products aimed at Healthcare Professionals should follow the rules in this chapter in their entirety.

CHAPTER 7 ADVERTISING AIMED AT HEALTHCARE PROFESSIONALS

Subsection 7.1 General requirements

Statements concerning effects should be based on quantified effect parameters and terms such as "unique" or "optimal" should not be used without valid references.

It is not permitted to claim that a Medicinal Product has placebo side effects. Claims such as "well-tolerated" must be supported by valid scientific references and followed by relevant information on the most important and/or most common side effects.

One may not simplify, omit or select ("cherry picking") information so that the Advertising is suitable to mislead.

Design of advertising

The advertisement must be balanced with regard to the product's benefit and risk and must always balance positive messages about effect with relevant safety information that helps to avoid incorrect use of the Medicinal product.

Safety information must be given such space, font size and emphasis that the information is balanced against the effect message and perceived as a naturally central part of the advertising message.

Safety information must be seen in connection with the provision on mandatory information.

If the advertisement mentions the area of use of the medicinal product, the relevant part of the indication text must be included in the advertisement itself.

If the Advertising mentions reimbursement for one or more indications, the Advertising itself should contain information on reimbursable use, reimbursement codes and terms for the same indications as the Advertising mentions.

Advertising for antibiotics should highlight the precautionary principle in SPC 4.1, that the use of antibiotics should be limited and that national guidelines should be followed.

The font size and contrast of mandatory information should be such that the text is readable by people with normal vision.

At physical meetings where, for example, you have Advertising on a roll-up, mandatory information should be available in the immediate vicinity

and possibly also available via a QR code on the roll-up. The same applies to sales presentations / slides.

It is sufficient to date an ad with month and year.

Subsection 7.2 Mandatory information
By "relevant" means that the information is adapted to the purpose and target group of the advertisement.

When the recipient of advertising is the prescriber, prescription-relevant information is particularly relevant.

When advertising is directed at Healthcare Professionals other than prescribers, such as pharmacists or nurses, other information, such as the method of administration, may be particularly relevant.

"Adequate" means that the mandatory information must be comprehensive and complete enough that the recipient is able to make up an opinion about the therapeutic value of the pharmaceutical.

"Complies with" the SmPC means that the advertisement must be in accordance with the information in the SmPC, see section 4.2.

What is to be regarded as relevant, must be considered specifically in each individual case.

The material should as a minimum contain information about:

- *Name and active substance of the medicinal product*
- *At least one approved indication. When advertising for specific indication (s), the rest of the mandatory information must relate to this indication (s).*
- *A brief summary of the dosage and usage.*
- *Safety info, this could be contraindications (info on which patients that can't use the product), side effects or precautions,*
- *Regulatory warnings, such as the black triangle.*
- *Prescription status and possibly prescription group*
- *If the medicine has particular prescribing rules, it should be included.*
- *An encouragement to consult the Felleskatalogen-text or SmPC for more information.*
- *Marketer's name and contact information.*
- *Date of design of the advertisement, view section 7.1.*

Dispensing provision
By the term dispensing provision, means that one must include a dispensing provision that is imposed on certain medicines, see information on the Norwegian Medicines Agency's website.

Price and refund

- *Price is normally stated as list price (maximum pharmacies' retail price «AUP»). Price is stated for the packages that are relevant to the indication the advertisement mentions.*
- *If the medicinal product is included in a tender, it should be listed which tender the medicinal product is part of (e.g., LIS 2007), in order to inform the recipient that the list price in this case is discounted. It can also be informed that the price is discounted. The discounted price is often considered a trade secret and should not be disclosed. Member companies may consider stating the ranking in tenders.*
- *By pre-approved reimbursement means reimbursement according*

to the prescription regulations ("blåreseptforskriften") of 28 June 2007. It should appear from the advertisement if the medicinal product has been granted a Norwegian marketing authorization and list price and is awaiting reimbursement. Any terms of refund must be included in the advertisement.

If the medicine is financed by a hospital (h-prescription "H-resept"), it should be stated whether Beslutningsforum has decided to introduce it to the market". In the time between the medicine has received a Norwegian marketing authorization and list price, but before a decision in "Beslutningsforum" has been made, it should be stated that a decision from the "Beslutningsforum" is awaited. All terms from «Beslutningsforum» should be included.

Subsection 7.3 Reminder advertisements

Reminder advertisements should not contain images and preferably no text beyond that mentioned, i.e. the preparation's name, the generic name of the active ingredient and the marketer's name. When a reminder is digital, "read more" and "for HCP's only" may be added. Information regarding digital frontpages, view section 5.2.1

The Rules are not opposed to referencing more than one Medicinal Product in one Reminder Advertisement, providing other content and shape demands are adhered to.

Subsection 7.5 "New/News"

Basically, a drug is generally available once the company has introduced the drug to the market; (MT & price & available in pharmacies). If a company starts advertising at that point, time begins to run.

In some cases, public funding may be crucial to ensure access to the relevant patient groups, e.g., decisions from decision-makers (Beslutningsforum). If the company starts sales promotions from this date, the deadline runs from then.

Subsection 7.6 Requirements relating to documentation

The requirement for documentation of information that is included in the advertising also applies to slogans and statements expressed visually. For example, claims such as "first" and "only" may be used if they can be documented.

References should normally be published in print or electronic form. Valid references in Promotional materials aimed at Norwegian Healthcare Professionals should be in Norwegian, Swedish, Danish or English.

References should, as a main rule, appear in the same viewing area as the claims the references aims to document. It may, however, in some instances, be purposeful, for example in a presentation, to reference everything collectively towards the end.

Subsection 7.7 Valid references

Valid references for claims about a Medicinal Product's properties and effects must be scientific works that are accessible by the recipient of the Promotional material.

A company's internal research reports do not meet the requirement for valid references.

Scientific is understood as systematic,

methodical and critical investigation, study or research which employs scientific methods. Scientific method normally requires that the scientific assertions are publicly and intersubjectively verifiable.

It is permissible to use official statements or reports published by Norwegian or joint-European pharmaceutical authorities as references. For example:

- *European Public Assessment Report (EPAR)*
- *Norwegian Pharmaceuticals Handbook for Healthcare Professionals*
- *Official Norwegian or joint-European (EU/EEA) treatment Guidelines*

Patient cases, fictitious or real, can be used to describe the disease and treatment of the relevant patient group. Any mention of Medicines must comply with the approved SPC, cf. section 4.2, And with the Rules in general. Patient cases should not be used to make claims about the properties or medicinal value of medicines.

When presenting sales figures and market shares, Farmastat or similar may be used as references. The premise used as a basis for the calculation must be clearly shown and a robust and verifiable calculation, which can be demonstrated on enquiry, must exist.

When using data from non-interventional trials/registered trials or similar, it must be clearly marked that these are not results from randomized controlled trials/pivotal trials and all necessary provisos must appear in the Promotional material.

There should be no biased focus on (individual) findings from supplementary trials.

In cases where the SmPC is being referred to, the section number should be given – e.g., 'SmPC, section 5.1' – if this is considered necessary to find the basis for the claim. It is not necessary to update the SmPC-date if the update does not mismatch the content of the ad.

References should appear as described in The guidelines for authors in The Journal of the Norwegian Medical Association.

Subsection 7.8 Quotations

All quotations, figures and tables must be accurately reproduced. Modifications may be made only if they do not interfere with the principal message of the original article, or if changes are necessary in order to avoid breaching the Advertising Rules.

When using trials, the main conclusion of the trial should, as a rule, always be presented, unless it is assumed to be wellknown or there are compelling grounds for excluding it. Secondary results may be presented as long as they do not present a false picture of the Medicinal Product's properties. Likewise, real clinical endpoints should always be emphasized in preference to surrogate endpoints.

It is recommended that underlying trials be used in place of summaries wherever possible.

When using references, the article's scientific objective should be taken into account. Information should not be taken out of its context in a misleading manner.

All data that directly or indirectly concerns the Medicinal Product's clinical effect or safety profile should include statistical calculations. The number (n), confidence interval, p-value and point estimate should always be stated where these are published. Otherwise, it must be clearly shown that no statistical calculations have been made.

Subsection 7.9 Comparative Advertising

Comparative Advertising must be designed in accordance with the rules in Regulation No. 1653 of 19 December 2000 on comparative advertising.

Only trials that have been carried out with the intention of demonstrating a difference may be used when comparing the effects and/or safety of Medicinal Products. Consequently, it is not permitted to present one's own comparisons or random findings as trial results.

Comparisons of clinical effects and/or safety comparisons should, as a rule, only be made by presenting data from directly compared randomized clinical trials.

Particular caution should be exercised when using registered trials in product comparisons, and registered trials should not be used as the only evidence for comparisons between the properties and effects of Medicinal Products.

Cochrane analyses may be used as a basis for comparative Advertising, but even then, necessary caution must be applied when considering what the analyses can be used to validate.

Beyond this, meta-analyses or review articles which present differences in clinical effects or safety profiles may be used only where they support data from directly compared trials.

CHAPTER 8. DISEASE AWARENESS

A Member Company's statements in relation to health or illness issues when not directly or indirectly connected to statements pertaining to one or more Medicinal Products is not regarded as Advertising.

Such statements directed towards the public serve the purpose of informing, increasing awareness or promoting learning with regards to a health subject or a condition or disease.

Information must be adapted to the target audience.

CHAPTER 8 DISEASE AWARENESS

These guidelines are in line with NOMAs guidelines on the subject. Emphasis should be placed on disease awareness rather than on information relating to treatment options. The information must reinforce the idea that it is the Healthcare Professional together with the patient who should decide on suitable treatment given the individual patient's unique conditions and requirements.

The information may refer to various treatment options. This means that the use of Medicinal Products may be mentioned as one possibility among several different alternative treatments. As a rule, there will be no opportunity to mention product names or specific active ingredients.

Medicinal Product groups may be

mentioned in health and disease awareness provided that it only refers to medicine groups at the highest possible ATC level (1 and 2).

Disease awareness should not promote the use of one or more specific Medicinal Products. Layouts or graphical elements in material which could be associated with specific Medicinal products must be avoided.

Non-advertising
Health and disease awareness should not advertise Medicinal Products nor should it bear the hallmarks of Advertising. Images or illustrations, including branding, colors or layout, which depict or refer to a specific Medicinal Product should not be used. Branding refers to the use of logos, graphics and other means with the intention of bringing to mind a specific product.

Information must not be phrased or shaped in a way making the target group think it is advertisement for one specific Medicinal Product.

Particular diligence is called for when discussing diseases with few treatment options. Disease awareness relating to illnesses with only one or a few alternative pharmaceutical treatments will possibly draw attention to one specific Medicinal Product, regardless of whether or not it is referred to. In such cases, it is especially important that the information does not focus on treatment but rather on health and disease and where one can turn for advice.

In case of new and important disease information this should be implemented in and replace previous releases. An online publisher should do its utmost to ensure that all information is always updated and dated.

Health and disease awareness should:

- *be medically correct,*
- *be dated and medically up to date. Where there is knowledge of new and significant health and disease awareness, this should be implemented in or replace earlier publications. The publisher of online information should do their utmost to ensure that it is always datestamped and up to date*
- *be verifiable; all information should have references or refer to reliable and academically peer- reviewed scientific sources,*
- *cover all the most important signs and symptoms of a given disease and not just individually selected aspects. The format of the information*
  33
  must conform to quality requirements and not the other way around
- *be suitable presented, have suitable design and format,*
- *ensure that the coping with the disease is presented in a balanced manner,*
- *not over-emphasize single risk factors, but rather present the risk factors in a complete risk assessment for the disease.*
- *not wrongfully emphasize particular treatment methods or a need to seek treatment.*

By verifiable, means that the recipient is made capable of re-discovering the basis for the information. It is not sufficient to distribute the documentation upon request.

However, obvious facts do not require references; for example, the statement "smoking is unhealthy".

CHAPTER 9. PRESS RELEASES

A Member Company may use press releases to communicate to the press in the same way as other businesses. The Member Company must, however, exercise particular caution to avoid the press release being seen as Advertising. This is especially pertinent when the press release involves product names or specific active ingredients.

In order for a press release not to be viewed as Advertising according to these Rules when it involves product names or specific active ingredients, it is recommended that the following requirements be satisfied:

- the press release concerns a news item having significant general newsworthiness,
- the mention of product names or specific active ingredients are kept to a minimum,
- only factual and brief information about the Medicinal Product must be given,
- the target group of the press release is the media,
- the press release is sent to, or put at the disposal of a group of journalists or media with a view to it
  being journalistically evaluated and processed prior to publication.

CHAPTER 9 PRESS RELEASES

This chapter applies to all information involving discussion of product names or specific active ingredients that is proactively sent, or put at the disposal of, the media; in other words, it also applies to any press notes, fact files or similar which accompany the press release.

The chapter applies equally to the content, design and distribution of the press release.

It is of no significance whether the discussion of product names or specific active ingredients is connected to prescription or non-prescription Medicinal Products.

If something described as a "press release" attracts payment, it will no longer be regarded as a press release but as a Promotional material and should follow the rules on Advertising.

Answers to questions from the media for their preparation of a news item are not dealt with in this chapter.

This guide can serve as a guideline for press handling in general.

a) significant general newsworthiness The news to be conveyed should have significant general newsworthiness.
This means that, in the first place, it must be a real news item being conveyed and that the purpose of the press release should not be to bring to mind a product or treatment nor to reach out with a promotional message.
The assessment of newsworthiness can be a difficult one. The assessment of newsworthiness can appear somewhat differently depending on which section of the media the press release is sent to or

made available to – cf. d) and e). A higher degree of general newsworthiness is demanded for a press release being shared with journalists from the general media than for one that can be shared with journalists in relevant academic journals. Be mindful that a news item is normally regarded as having newsworthiness for a limited time period. This can vary and must be properly assessed.

b) *discussion of product names*
Mention of product names or specific active ingredients should be kept to a minimum and should be used only if necessary. Such discussion may be necessary for the communication of the news item itself, for example, or in order to elucidate that the sender of the news item has products within the area to which the news item pertains.

If it is necessary to mention the product name, it is recommended that this be limited to one statement.

c) *factual and brief*
The press release should be neutral and not come across as promotional.

Any use of images should be neutral and factual. Sensationalist words and emotional patient stories should be avoided. A press release should not contain leads as to how the recipient should respond to the information.

All information about a Medicinal Product should be based on facts in the form of technical information, information from the SmPC or package inserts or trial results.

A press release is not advertising, nor should it come across as Advertising.

d) *target group*
A press release should be marked "press release" and should be clearly distinguishable from the Member Company's marketing material.

Its linguistic style should be clearly directed towards journalists or editors in the relevant media.

e) *distribution of press releases*
Press releases may be sent directly to relevant journalists or contact persons, or be made available for a limited time period in other channels where the target group is comprised exclusively of the media.

Press releases disseminated by any other means will normally be viewed as marketing (Advertising).

There are no specific requirements how references should be reproduced by this chapter.

Information may be provided for disease to be recognized and to enable patients to be better informed in meetings with Healthcare Professionals. However, only doctors (or other qualified Healthcare Professionals) are qualified to make diagnoses. It is important that information cannot be interpreted as guidance for self-diagnosis.

If reference is made to screening, testing (e.g., yes/no questions about symptoms or biological tests), medical equipment or similar, it must be made clear that any outcome alternatives do not anticipate or give a definitive diagnosis, and a recommendation should be given to contact a doctor or other qualified healthcare professional.

Symptoms should never be described in such a manner as to "create" patients.

The originator must be clearly shown. All printed material must bear the name of the publisher of the information. Company profiling, however, should not be the main focus.

This also applies to health and disease awareness online but not on companyowned pages.

CHAPTER 10. STOCK EXCHANGE ANNOUNCEMENTS

A Member Company that is listed or, moreover, has a duty to report under securities legislation may, without impediment of these Rules, fulfil its legal obligations. Any mention of product names or specific active ingredients should be kept to a minimum.

CHAPTER 10 STOCK EXCHANGE ANNOUNCEMENTS

Securities legislation has provisions which require that listed companies immediately and of their own accord make public any inside information that directly concerns the company. Such information should also be placed on the company's website.

This means that information subject to such notification requirements should be made public even if it would represent a breach of the ban on pharmaceutical advertising or other pharmaceutical regulatory rules for companies without an obligation to report.

The information is limited to inside information that is required based on disclosure requirements in the Norwegian Securities Trading Act.

These provisions will probably, from a practical point of view, come into force only for companies registered on the Oslo Stock Exchange, but they will of course apply to all companies that are subject to a lawful duty to disclose the facts.

CHAPTER 11. PROHIBITION ON GIFTS

It is forbidden to give, offer or promise gifts, personal favors, or pecuniary advantages to healthcare professionals except in the circumstances provided for expressly.

The prohibition on gifts also includes inexpensive promotional items such as pens, mouse mats and post-its.

CHAPTER 11 PROHIBITION ON GIFTS

Applicability
The prohibition on gifts does not include information and educational

material or medical utility items providing that they are of low value, as referred to in Chapter 12.

Promotional material such as direct mail, brochures are not considered "gifts" and may be distributed.

Absolute prohibition on gifts
All forms of gifts are prohibited. The gift prohibition includes all benefits without an equivalent benefit of the same value being reciprocated. This also includes flowers related to the marking of professional and private occasions.

Inexpensive gifts to a doctor who has given a talk, for example, are also prohibited.

The gift prohibition also covers loans to healthcare professionals, such as a free loan of computer equipment.

The prohibition on gifts also includes indirect gifts. Gifts might be tickets to a sporting or cultural event, money or items equal to money, such as coupons or vouchers.

Office equipment
It is prohibited to give pens, mouse mats, notepads and so on.

At meetings at Healthcare Professionals' workplaces, it is permitted to make practical meeting equipment such as pens and note pads available to participants, on condition that such equipment not be marked with the name or logo of a company or product, and that it be of insignificant value.

At company meetings held at the company's own or hired premises, pens and notepads with the name and/or logo of the firm (not a product) may be used.

However, these rules do not preclude hotel or convention Center names from being printed on meeting equipment.

CHAPTER 12. MATERIAL AND MEDICAL UTILITIES

12.1 Information and educational material
Information and educational material may be distributed to healthcare professionals on condition that the material is of low value and of direct professional significance for medical treatment or pharmacy practice and of direct use for the treatment of patients.

12.2 Medical utilities
Medical utilities may be distributed with the aim of promoting the education of healthcare professionals and patient treatment, on condition that they are of low value, and of direct professional significance for medical treatment or pharmacy practice and of direct use for the treatment of patients and are not a part of the recipient's usual professional activity such as consumables and other items necessary for the operation of the healthcare professional's activity.

12.3 Medical aids for patients
Healthcare Professionals may receive information and educational material or medical utilities of low value that may be handed on to the patient.

12.4 Company name and logo
Such products can portray company name and logo, but must not include product name or known signs unless it is important to ensure correct usage of the product and a part of the material's function or purpose.

This typically applies to "dummies" (empty inhalators) that are marked with "for

demonstration" and "does not contain an active substance".

12.5 No conditions

Materials and utilities referred to in this chapter may not be offered or distributed on condition of a consideration of any kind from the healthcare professionals, such as holding a meeting.

12.6 Risk Management Plan

This chapter does not apply to information material or medical utilities which are a part of the Risk Management Plan for Medicinal Products.

12.7 Definition of 'low value' and how it relates to the gift provision

'Low value' in this chapter is defined as a maximum amount set by the board of the Association of the Pharmaceutical Industry in Norway (LMI).

The gift prohibition regulation in Chapter 11 is no hindrance to the distribution regulations in this chapter.

CHAPTER 12 MATERIAL AND MEDICAL UTILITIES

The rules do not have any annual cap or further limits for distribution. Requirements for relevance and usefulness set clear limits for the distribution of such items. The general prohibition on gifts in chapter 11, the Healthcare Professionals Act § 9 and Regulation on HCP's limitations to receive gifts should also be noted. Also pay attention to Circular I-13/2005 concerning the regulations on restrictions on healthcare professionals' right to receive gifts, commission, services or other benefits and the statements therein about the value of work-related gifts (see p. 27). It is important that companies ensure that the combined value of information and educational material does not exceed what the authorities consider acceptable.

CHAPTER 13. EVENTS ORGANISED BY MEMBER COMPANIES

13.1 Scope

This chapter applies to events organized by one or several Member Companies. This chapter applies to events regardless of what they are called or which physical manner they are conducted and include advertising meetings, medical meetings, symposiums, webinars and professional outings.

13.2 Content requirements

The main purpose of any event encompassed by this chapter should be the updating of professional knowledge.

13.3 Participation

Member Companies should, as a rule, meet with groups of relevant people. This does not preclude the possibility of meeting with individuals for practical reasons.

In interdisciplinary meetings with advertising for prescription drugs Other Healthcare Professionals may participate, provided that (i) Healthcare Professionals defined in 1.5 are present and (ii) the employer assesses that there is a professional need for participation.

13.4. Requirement for professional

relevance Prohibition on companions Only persons who are qualified and have the relevant professional interest in the meeting may be invited to participate.

Companions are not allowed, unless significant medical reasons require so.

13.5 Invitation requirements

Requirements relating to invitations where medicinal products are discussed (ad

meeting, medical meetings etc.) to Healthcare Professionals, should include the following information:

- Time and venue of meeting, alternatively log on information,
- Professional program and its duration
- Specification of any expenses to be covered and meal provisions
- The date the invitation was prepared
- Mandatory information (cf. subsection 7.2) for all Member Companies' products mentioned in the invitation
- Information on the treatment of personal data
- The source of address registers (if address registers are used)
- Information on who may participate in the meeting
- Information on the disclosure of transfer of values in connection with the meeting, where relevant (cf. Chapter 24)

If meeting invitations are sent to employees of health authorities the invitation should make it apparent that the employee must obtain permission from their employer to participate in the meeting and that the health trust (when relevant) must cover the associated travelling and accommodation costs.

Meeting invitations containing an agenda should be approved in accordance with the Member Company's procedure for approving Advertising (cf. subsection 26.2).

The requirement for invitation under this provision does not apply to promotional visits. Promotional visits are defined as brief meetings, with a sales representative or other company representative at the healthcare professional's workplace or through digital channels, usually during working hours.

CHAPTER 13 EVENTS ORGANISED BY MEMBER COMPANIES

Subsection 13.1 Scope
The rules apply to all types of events. Webinars and other types of direct procurement of events via digital media organized by a Member Company must comply with all rules in chapters 13 and 16, also in cases where the Member Company's representatives do not have the opportunity to be physically present with all participants. For example, a professional event can be held with participants in Oslo, whilst participants at a health institution elsewhere in the country are simultaneously involved in the event via digital participation. In such cases, standard rules for events will apply, including subsection 13.5, chapter 16 and subsection 26.4.

Member Companies can also arrange professional courses/visits at a hospital clinic or such like abroad, for example, for a small number of healthcare professionals. (This type of activity is also referred to as "spesialist turer").

The course must be academically relevant to the participants.

Advisory Boards are regulated in separate chapter.

Subsection 13.3 Participation
As a main rule, only Healthcare Professionals according to section 1.5 (doctors, dentists, publicly approved nurses, pharmacists, opticians, dental nurses, as well as students in these subjects), can participate in meetings containing advertising for prescription drugs.
Other Healthcare Professionals as defined in section 1.6 (e.g. pharmacy technicians, health secretaries, radiographers, clinical nutritionists, physiotherapists), etc. may however

participate at interdisciplinary meetings where prescription drugs are being advertised if:

1. *the meeting is interdisciplinary,*
2. *Healthcare Professionals as defined in section 1.5 are present and*
3. *the Other Healthcare Professional employer assesses there is a professional need for participation.*

Apart from information sharing in such an interdisciplinary meeting, advertising of Prescription Medicines to Other Healthcare Professional as stated in 1.6 is prohibited.

A meeting invitation is often considered Advertising and can in that case only be sent to Healthcare Professionals as stated in 1.5. When an invitation is to be regarded as Advertising, Other Healthcare Professionals must be notified of the interdisciplinary meeting at their workplace / by their employer.

The employer of Other Healthcare Professionals must based on the invitation assess if there is a professional need for participation. The company can ensure this is assessed by, for example, asking for feedback on who is to attend the meeting, and in that way assume that the participant has clarified participation with their own employer.

Member companies must consider how dialog around or meeting invitations to interdisciplinary meetings are designed. Suggested wording:

«This meeting/sales rep meeting may also be relevant to other healthcare professionals than doctors / dentists / (...). Other healthcare professionals may participate in this interdisciplinary meeting, even if prescription drugs are discussed, if the healthcare professional groups listed above participate and the employer consider that there is a professional need for participation from other healthcare professionals. Please provide feedback to whom from your workplace that wish to attend the meeting. "

Other meetings than interdisciplinary meetings may be held for professional groups that are not Healthcare Professionals as defined in section 1.5, as long as the meeting is relevant and does not contain Advertising for prescription drugs. These professional groups can receive professional training e.g., in spirometry, or general health education about disease awareness.

Subsection 13.4 Prohibition on companions

The prohibition on companions applies even if the companion were to cover all expenses themselves. The prohibition does not apply to user-controlled personal assistance etc. when significant medical reasons require so.

Subsection 13.5 Requirements relating to invitations to Advertising Meetings

Note that if students (those included under the definition of Healthcare Professionals) are to be invited, many educational institutes need to be informed and give their approval for attendance in advance.

By other company representative, means for example medical advisor.

Neither digital nor physical consultant visits require an invitation in accordance to section 13.5. A booking is sufficient.

The invitation requirements do not prevent digital placeholders / save the date / booking letter etc.

For information on digital invitations to hospital employees to company-arranged meetings, see guidance section 15.2.

CHAPTER 14 EVENTS ORGANISED BY THIRD PARTIES

14.1 Scope

This chapter applies to professional events under the direction of a third party which are completely or partially financed by one or several Member Companies, for example the purchase of advertising or a stand.

This chapter applies to all such events regardless of what they are called and include scientific meetings, congresses, conferences, trade days and symposiums, including where these events are being conducted digitally.

14.2 Permitted third-party events

A Member Company may financially contribute to events encompassed in this chapter if they are arranged by a legal entity (i.e., the organizer must have an organization number).

In addition, the following criteria should be met:

(i) The event's main purpose should be to update professional knowledge.
(ii) The academic content of the event is managed by an independent committee or equivalent.
(iii) The Member Company should not influence the professional content of the event.
(iv) More than one Member Company should be invited to participate in/contribute financially to the event
(v) A Member Company cannot demand to be only sponsor at an event.
(vi) The event should be carried out in a restricted area so that only Healthcare Professionals are exposed to Member Company Promotional materials/stands where it is advertised for prescription-only Medicinal Products. If the event is held digitally, it must be ensured that only Healthcare Professionals are being exposed to prescription drugs advertising.
(vii) The event fulfils the requirements pertaining to events and hospitality in these Rules; refer in particular to Subsection 13.4 (Professional relevance) and Chapter 16 (Requirements for professional program, venue, meals, coverage of expenses).
(viii) Agreements concerning the purchase of advertising or a stand at events under the auspices of a third party must be concluded in writing.
(ix) The Member Company must not contribute practical or administrative assistance with the execution of the event.

Special rules apply for events organized by health authorities – see Chapter 15.

Special criteria apply to the financing of events organized in Norway by Norwegian Healthcare Professional Associations – see subsection 14.3.

14.3 Meetings organized by Healthcare Professional

Special criteria apply to the financing of events organized in Norway by Norwegian Healthcare Professional Associations.

14.3.1 Concept approval

A Member Company may contribute financially to events organized by Norwegian

Healthcare Professional Associations only if the event's concept has been approved beforehand by the Committee's secretariat.

A Member Company must quarterly notify the LMI about the financing of a conceptapproved event, by sending an e-mail to soknader@lmi.no

Concept number is required. Where this is not possible the company may state the

name and date of the event. Member companies must not inform LMI of the contribution's content, scope or nature.

The LMI subsequently invoice the Member Company an amount determined by the Board depending on per event that the Member Company finances.

The Healthcare Professional Association is responsible for applying for concept approval.

14.3.2 Criteria for concept approval:

i) All criteria in subsection 14.2 should be met:
ii) The Healthcare Professional Association organizing the event is a registered association with Norwegian organization number.
iii) Travel, board and course expenses for participants will be covered by the participants themselves or their employers, not the organizer.
iv) The meeting will take place in Norway or if a digital event where Norwegians HCPs are being targeted.
v) The budget shows that the event will earn a maximum profit of 10% on the income.

If the collective contribution from all Member Companies is less than 10% of the event's total budget, the Secretariat may, on further evaluation, still approve the concept even if the criteria in 14.2 (vii) and 14.3.2 (v) are not met.

Refusals must be justified. Approved applications will be published on Digitalis.

14.4 International congresses

Large international congresses (> 500 participants from a minimum of 5 countries) are approved by EFPIA, https://www.ethicalmedtech.eu/e4ethics/about-e4ethics/

14.5 Third-party events abroad

It is not permitted to finance participation, travel or stay for Healthcare Professionals attending events abroad which have been organized by a third party. It is not permitted to finance full participation fees to digital events organized by a foreign third party.

Nor is it permitted to contribute to trips affected by the prohibition in the first paragraph by way of offering direct or indirect support, practical assistance, travel grants or general assistance to employers or by any other means.

The prohibition however does not preclude a Member Company from inviting Healthcare Professionals to company-organized meetings at international congresses in accordance with Chapter 13.

CHAPTER 14 EVENTS ORGANISED BY THIRD PARTIES

The stipulation of "professional event" should be widely understood to cover all types of events within the sphere of medicine, research, pharmaceutics and patient treatment. This chapter does not encompass political or socio-economic meetings.

A Member Company's contribution could consist of purchasing advertising (including advertising space, such as company logo, in association publications and the inclusion of Promotional materials in an association's circulations) or the purchase of exhibition stands or of permits to organize satellite symposiums. The purchase of advertising space should not generate a misleading impression that the industry is a co-organizer; for example, company stands should be positioned outside meeting rooms, and any logo on an invitation or other meeting equipment must be positioned such

that the company does not appear to be the co-organizer.

Subsection 14.2 Permitted third-party events
A third-party events must be organized without influence from the Member Companies.

Subsection 14.3 Events arranged by Healthcare Professional Association
For more information about Concept Approvals, please view LMIs homepage.

Applications that have not been granted approval will not be announced on Digitalis.

The LMI will invoice the Member Company for each event the Member Company finances. The fee is NOK 1000.- (per 2023) and is invoiced quarterly.

Employees in Member Companies may exceptionally participate as regular paying course participants in courses that provide CME credits in doctors' continuing medical education, when the purpose is professional update. It is the organizer who assesses whether there is room for industrial participation.

Such participation, provided that the participation fee for an employee of the Member Company is the same as for other course participants, is not considered a contribution/financing of an event organized by a third party.

Subsection 14.5 Third-party events abroad
The Rule in this subsection (14.5) is often referred to as "the congress decision" because the reason for its inclusion was to prohibit a Member Company from financing travel, board and congress fees for Norwegian doctors attending international congresses outside Norway.

Paying for or facilitating fully digital access to conferences is a breach of the congress decision. However, one may pay for/facilitate digital access to individual talks held at third-party events abroad.

Own professional meetings at congresses If local rules at a congress venue allow it, a Member Company may send out invitations to their own professional meeting at a congress. The meeting may not be held at a time which would prevent participants from taking part in the congress's professional program. The meeting may not be held as an extension of the congress if this would require extended accommodation at the congress venue. Terms s ch as "after congress" etc. could give rise to unfortunate associations and should be avoided. Whenever practically possible, it is preferable for several companies to be involved in such meetings.

All the Rules for meetings organized by Member Companies (cf. Chapter 13) will apply. Meetings should, for example, meet the requirements for Norwegian conferences – i.e., at least 90 minutes of scientific program if there is an invitation to a meal after the meeting. Any hospitality should be modest and in accordance with local rules at the congress venue.

Invitations to the professional meeting may be sent to Healthcare professionals who will be attending the congress before their departure from Norway. Information that the company will be present at the congress, and possibly details of

exhibitions and professional input/offers from the Member Company, may also be sent out.

Investigator meetings for Norwegian trials should not be held at foreign congresses unless participants are already at the congress and the member company does not cover travel expenses or accommodation.

In the case of international trials, it may be necessary to take part in investigator meetings which are held at congresses. It is not possible to cover travel and/or accommodation beyond what is strictly necessary for participation at these trial meetings.

"A Norwegian evening" hosted by a thirdparty
In accordance with point 14.2, Member Companies can support meetings cohosted by a third-party.

By a third-party host, means, for example, that they are professionally and administratively independent from the Member Company and that the third-party has the financial responsibility of the event.

CHAPTER 15. SPECIFICALLY CONCERNING CONTACT WITH HEALTHCARE PROFESSIONALS AT PUBLIC HOSPITALS (HEALTH AUTHORITIES)

15.1 Requirements relating to appointments

Meetings between company representatives and employees at the Health Trusts (Helseforetak) must always be agreed in advance in accordance with the health trust's authorisation procedures.

15.2 Company arranged meetings

15.2.1 Invitation/Information
Information and invitations to courses, professional meetings etc. arranged by the Member Company must always go to the main e-mail (postmottak) at the health trust. Copies may be sent directly to employees and must comply with the rules for electronic communication. Participation shall not be reserved for a specific person unless agreed with the health trust.

15.2.2 Participation
Employees in the health trusts may participate in activities provided that the measure is approved by the health trust. Responsibility for clearance rests with the individual employee.

15.2.3 Travel and accommodation expenses

Travel and accommodation expenses in a professional context must be covered by the individual health trust. This provision does not apply to journeys over shorter distances where there is practical provision for public transport. Moderate dining in connection with professional events may be permitted, cf. section 16.4.

15.3 Competence enhancement

The purpose of cooperation is the exchange of knowledge and competence enhancement.

15.3.1 Lecture/lecturer at professional meeting organised by health trusts
Member companies may, by agreement, lecture or contribute with the lecturer at internal professional meetings organised by the health trust. Members may also offer their expertise through the health trust's supplier contact (leverandørkontakt).

15.3.2 Co-organizer of meetings

Member companies may, by agreement, be co-organizers of professional meetings, courses, congresses or similar.

It must be clear from the material that the Member Company is a co-organiser. It must be stated that the event has been approved by the health trust.

Both the health trust and the member company are responsible for the content. The meeting will be subject to the same rules that apply to company-arranged meetings.

15.3.3 Stand rental

Member companies may enter into agreements on the rental of stands in connection with professional meetings etc. arranged by the health trust.

15.4 Training of patients and relatives

Agreements may be entered into for patient and next of kin training, e.g. preparation of patient brochures or education and training through self-management centres or other measures.

CHAPTER 15 CONTACT WITH HEALTHCARE PROFESSIONALS IN HEALTH TRUSTS (PUBLIC HOSPITALS)

Section 15.2.1 Invitation/information

The condition for sending a copy directly to the employees is 1 - that the invitation has been sent to the mail mailbox and 2 - that consent to the use of electronic communication (see GDPR and the Marketing Control Act) has been obtained.

The health trusts may have different schemes for distributing invitations. In order to reach more recipients, companies may also send invitations to supplier contacts or in accordance with the hospital's procedures. In this case, the invitation should be marked with the respective department.

CHAPTER 16. REQUIREMENTS FOR PROFESSIONAL PROGRAMME, VENUE, MEALS, COVERAGE OF EXPENSES

16.1 Choice of venue and destination

All events should be held at an appropriate venue and destination in respect of the meeting's principal professional purpose. No events should be located at destinations which are associated with sporting or leisure activities, or which have a reputation for being extravagant.

Events should take place in Norway, unless:

a) the majority of invitees are from countries other than Norway and the destination seems reasonable given the place of residence of the participants, or

b) the location of the organizer or expertise makes it more sensible to hold the event outside Norway.

c) the location of the participants makes it more sensible to host the meeting outside Norway.

16.2 Hospitality

Hospitality offered by Member Companies is only allowed in connection with events as mentioned in Chapter 13 ("Events organized by Member Companies"), 14 and 15. The rules in this chapter also apply to work meetings in connection with consultancy services and clinical trials.

Hospitality must be limited to travel, meals and accommodation.

16.3 Reasonable and necessary

Hospitality offered by Member Companies must be reasonable in scope and size and a pre-requisite of the professional program.

Specific rules apply when catering a digital event/meeting, view guidelines.

Dinner according to rate B, cf. point 16.5, can be served at the earliest when the 90-minute academic program has been

completed. This does not prevent a simpler meal being provided prior or during the meeting.

Financing, organizing or facilitating entertainment or social activities is prohibited.

16.4 Meal rates

16.4.1 Rates in Norway
Catering rate A shall constitute 50% of the State's rates for "simpler lunch/reception".

Catering rate B shall constitute 80% of the State's rates for "lunch/dinner".

The rates include drinks and VAT, exclusive of any tips.

16.4.2 Rates outside Norway
The rates of the host country apply to events and work meetings abroad (as determined by the national association). If there are no locally decided rates in the host country, rates in this chapter must apply.

16.4.3 Serving of alcohol
The serving of alcohol beyond moderate quantities of wine or beer with dinner following meetings is not permitted. Alcohol must never be served at the workplace or in connection to digital events.

16.5 Terms for hospitality and requirements for content

Hospitality can only be offered in a professional context, cf. 16.2 Duration of the professional program, and the type of activity determines which hospitality rate is applicable:

- Hospitality rate A can be applied for promotional visits.
- Events/work meetings must include at least 45 minutes of professional content for hospitality rate A to be applicable.
- Events/work meetings must include at least 90 minutes of professional content for hospitality rate B to be applicable.
- Events/work meetings that include at least 5 hours of professional content can use hospitality rates A and B in combination.
- At events/work meetings that include at least 5 hours of professional content, and for which participants need to arrive the evening before due to the timing of the meeting, a meal may be served the evening before the meeting for up to 50% of hospitality rate B.
- For participation at digital events /Work meetings at which the Member Company's representative is not physically present, cf. 13.1, hospitality rate A applies, regardless of whether the meeting includes over 90 minutes of professional content.
- When participating individually at digital events/meetings, hospitality cannot be provided.

16.6 No other purposes

It is not permissible to facilitate tickets being used for other purposes than the meeting in question, in full or in part.

CHAPTER 16 REQUIREMENTS FOR PROFESSIONAL PROGRAMME, VENUE, MEALS, COVERAGE OF EXPENSES

Generally
Generally, the academic program must always be the main focus and there must always be logic and professional reasons for choosing a location and destination for events, as well as possible hospitality.

Common sense needs to be applied and the intention of the industry rules considered.

Aspects to consider when choosing a destination (geographically) and

location (meeting venue and restaurant):

<u>Destination: is the destination purposeful and practical?</u>

- *All destinations and locations used by a Member Company to host an event, must be appropriate and relevant in relation to the purpose of the event, based on professional and logistic criteria. The choice of destination and venue must not appear offensive, or in any way, provide the impression that the purpose of the meeting is anything but professional.*
- *When choosing a destination, the majority of participants´ logistic availability needs to be considered.*
  - *Local events (aimed towards participants from a town, city, municipality), should be hosted in the respective area to which the participants reside. In some scenarios, skiing destinations, or other destinations associated with leisure activities, holidays etc., might be applicable, if the healthcare professionals geographically reside to the area (e.g. Geilo).*
  - *Regional events (aimed towards participants from a municipality or county or large area) should be hosted in a non-controversial destination, providing purposeful and practical means of transportation. It must be emphasized that the destinations are considered natural regarding the participants´ working address.*
  - *National events, aimed at participants from throughout the country, should, as main rule, be hosted in one of the larger cities, or nearby one of the larger cities. Which city that is chosen, should, as main rule, depend on the geographical composition of the participants. However, a large majority from the chosen destination is not required.*
  - *Meetings hosted abroad by a Member Company - in addition to adhere to the common principles (geographically correct and cost responsible) when choosing a destination, should typical tourist destinations associated with sporting activities or other factors that might imply that other reasons than professional or logistics are taken into consideration, be avoided.*
- *Destinations and locations should be practically located for transport and parking. Facilities that are easily accessible via transport (time and cost), should be chosen. As an example, if the meeting is hosted in a venue in the city and subsequent dinner is at a restaurant within walking-distance. However, this is not a hinderance to schedule shorter transport options within the city, for example to and from the venue and restaurant.*

<u>Associated with leisure or culture activities</u>
The destination or location can be associated with, or itself be an attraction: For example, a skiing destination (Geilo, Hemsedal, Trysil etc.), boat, ferry, the opera, other concert venues, museums and sports arenas.

- *Professional conference venues or companies (including centers and hotels) should be prioritized.*
- *Meeting venues and restaurants*

located in concert venues, museums or sporting venues, should, as a main rule, be avoided, even though they might be practical. It must, when using such venues, be strongly considered which impression using such venue might leave. In this assessment, whether the venue itself is considered an attraction and whether the venue is part of a professional venue or center, or if there are any other suitable venues, can be assessed. If it is deemed necessary to choose such a location, the event needs to take place when it is not a sporting or cultural event happening.

- *If accommodation is required in connection to the meeting, it needs to be carefully considered whether the location or facilities might provide the contestant with an unduly advantage.*

<u>Facilities: are they suited for professional meetings?</u>

- *The meeting facilities must be suitable for information and discussion about Medicinal Products in a closed forum.*
- *The meeting facilities, regardless of whether they are in an event center or at a restaurant, needs to be adequately separated from common areas, to prevent that the advertisemeant for prescription-only Medicinal Products are not available to the general public, and that the meeting is hosted in professional and confidentially-adequately facilities.*
- *It should also be considered if there are adequate or better suited facilities available nearby.*

<u>Extravagance: can the overall impression of a venue appear "extravagant" or "luxurious"?</u>

- *The assessment regarding exclusivity, can be based on own marketing or information provided at the venue's website, or general reputation among the public. For example, a 5-star hotel, a gourmet restaurant with stars in the Michelin Guide, or described as "exclusive", "luxurious", etc., and portrays an illusion of extravagance, must not be used by a Member Company.*
- *The facilities' actual price level needs to be assessed in accordance to reputation.What you actually pay is basically not decisive. The general price level of the facility must be assessed with regard to reputation*
- *Check the website and reviews of venues/restaurants.*

In addition, the overall impression of the meeting invitation needs to be assessed, as it is the professional content that needs to be the focus.

Subsection 16.1 c

For example, hosting a Norwegian Evening at congresses abroad, constitutes a logical reason for hosting the event outside of Norway.

Subsection 16.2 Hospitality

Expenses related to work meetings may be covered in connection with, for example, consultancy services, cf. chapters 19 and 20. This requires a consultancy agreement to be in place, cf. chapter 19.

This also applies to employees of healthcare enterprises on condition that all expenses to be covered are referred to in the contract for the consultancy work and that the contract is cleared with the employer in accordance with the enterprise's rules.

<u>Serving on stand</u>

Serving on stand is permitted, if the

serving does not appear or function as a gift.

Examples of permitted serving: pieces of fruit, assorted chocolates, cookies, small brownies, simple coffee serving etc., that are suited for consuming on the spot.

Subsection 16.3 Reasonable and necessary

Hospitality must be reasonable in scope and size and strictly necessary to achieve the professional objective of the travel and/or event.

Hospitality must not exceed what the recipient normally would have paid if they had paid themselves.

<u>Digital events/meeting/sales rep meetings</u>
A Member company can offer catering at digital meetings if the following are met:

- *There must be a clear need for catering to ensure professional implementation.*
- *For catering to be an option the meeting must fall under one of the following alternatives:*
    a) *The meeting / event is held in the extension of working hours and lasts for at least 45 minutes*
    b) *the meeting is held during lunch, or*
    c) *the meeting has a duration of more than 4 hours.*

- *Catering must be clarified with the participants' employer; at meetings at Health Trusts, inquiries about catering must be directed to the supplier's contact. (leverandørkontakt) or the person authorized by the person in question in accordance with the authorization regime.*
- *It must be agreed that a person at the meeting place handles the practicalities (receiving refreshments, communication with the company about the number of participants, cleaning up, etc.).*
- *The meeting must be interactive and live, where communication can take place between Member Companies and participants.*
- *Participants must participate in groups from a suitable meeting venue at or outside the workplace. It is not allowed to cater participants who participate individually e.g., from workplace or home office.*
- *Catering must be limited to the confirmed number of participants.*
- *Catering rate A.*
- *A Member Company must ensure documentation of participants and catering in accordance with 27.4.*

<u>The prohibition of financing, organizing, adapt for or hosting entertainment or social activities</u>
A Member Company cannot host or facilitate for social activities or entertainment, nor can they contribute financially to professional events, hosted by a third party, where the third party is organizing or facilitating for entertainment or social activities. It may, however, appear scenarios where the third-party hosts facilitate for social events for the participants, when it is not part of the professional event. Whether this should precipitate that the company is committed to refuse participance, will depend on a total assessment of the situation.

Considerable factors may include:
- *The size of the meeting/event – for example, whether it is a professional congress lasting for several days*
- *Participants – for example if participants are such that also the*

industry should be represented as a natural part of the Norwegian healthcare service.

- *The size of the financial contribution, for example where the financial contribution by the industry is insignificant compared to the total budget*
- *Professional activities – for example where the professional activity by the industry is limited compared to the total program*

In every scenario, it needs to clearly state in every relevant area, including the program and website, that social activities are covered by the participants and in no way facilitated or financed by the industry. It is recommended that the member companies refrain from participation in social activities.

It must, in all scenarios, be conducted an overall discretionary assessment of loss of reputation. The risk for that, needs to be low.

Subsection 16.4.1 Rates
Rate A from January 1st 2024 is NOK 299.-
Rate B from January 1st 2024 is NOK 1,298.-

Subsection 16.4.3 Serving of alcohol
Serving of beer or wine with food is allowed in moderate amounts. Moderate is normally understood as 1-2 glasses. It is not permitted to serve alcoholic aperitifs or spirits.

Subsection 16.4.4 Terms for hospitality and content requirements
Member Companies hold many different types of meetings. In order to clarify when the two rates can be used, here are some examples:

a) Sales representative visits

A typical example of this type of activity is lunchtime visits from sales representatives. These meetings are normally held at the healthcare professional's workplace, with the pharmaceutical consultant providing the food. Alternatively, the meeting may take place in the hospital canteen. The meetings should be documented in line with subsection 27.4, but there is no requirement for an invitation in accordance with subsection 13.5.

If there are any doubts that a meeting is considered a sales representative visit or a meeting requiring an invitation (13.5), the following factors should be considered in the overall assessment: at what time of the day the meeting takes place (within ordinary working hours), duration of meeting, is the company representative accompanied by an external speaker (physically/digitally) or how many doctors are met with simultaneously.

b) Events with between 45 and 90 minutes of professional content
A typical example here is a one-hour advertising meeting that is held immediately after working hours digitally, at a healthcare institution or at a meeting venue close to the participant's workplace. The meeting must last at least 45 minutes if food is to be served. Choice of venue is regulated by subsection 16.1.

c) Events with at least 90 minutes of a professional program
This is a type of advertising meeting that is often held in the evening at a meeting venue and where dinner, where applicable, is eaten at a restaurant, cf. subsection 16.1.

d) Events with at least 5 hours of

professional content
A typical example here is an all-day meeting, regardless of whether participants arrive the same day or the evening before.

Combination of serving rate A and B can be made available as needed, however, so that not a single meal exceeds the serving rate B.

Food may be served the evening before provided that the professional program the following day is at least 5 hours long.
Please note that arrival the day before and overnight stays can only be offered when necessary due in example to an early meeting start for the speaker or the majority of the participants. Where the professional program is split over two days, standard hospitality rates apply for the corresponding program duration.

e) *Work meetings*
Examples of work meetings include meetings with consultants on an Advisory Board, meetings with the program committee or meetings with investigators in connection with a clinical study. For hospitality to be offered, a contract for the work must already be in place, cf. the guidance on subsection 16.2. The hospitality rates apply correspondingly based on the duration of the meeting.

For longer meetings, it may be relevant to serve light snacks prior to or during the meeting. Where initial light snacks are followed by a meal at a later point, these should not collectively exceed the relevant hospitality rate that corresponds to the meeting duration.

Further guidance on the chapter:
A professional program is defined as, for example, a talk on the therapeutic areas or specialist fields in which the Member Company operates, as well as product information. Professional programs can also consist of case discussions, workshops, group work, problem-based learning, guidance on self-care etc. within the therapeutic areas or specialist fields in which the Member Company operates.

If a collaborative meeting (such as a joint meeting with pharmacy personnel) is organized by several Member Companies or in cooperation with other companies, the requirement for 90 minutes of professional content applies to the event as a whole.

The requirement for 90 minutes of professional program prior to dinner does not prevent the serving of simple refreshments before the start of evening meetings, where such is necessary in practice. If such refreshments are served and dinner is subsequently served after the meeting, the cost of same must be included in the calculation of the total sum in relation to the maximum rates for dinner. This does not prevent the serving of both lunch and dinner at full-day meetings.

In addition to the mandatory duration for a required professional program, it is permitted to include shorter professional lectures/presentations on other topics related to the Member Company's or the audience's activities, including patient treatment. This may, for example, include talks on law related to patient records, training in internet searching for medical information etc. This part must be given a subordinate place in the invitation and the program and must be in

addition to the mandatory duration for the required academic program. Lectures or presentations that must be considered entertainment or that are social in character are not permitted.

CHAPTER 17. DONATIONS

17.1 Donations and grants etc.

"Donations" are defined as objects of value, service or pure financial contributions given by a Member Company without the recipient providing reciprocation.

Donations, as defined in this chapter, may only be made to Healthcare Organizations. The Rules in the present Chapter, do not apply when a Member Company, equally to any other business, supports haritable/nonprofit/ socially beneficial causes, which are not directly or indirectly connected to the company's activity as a manufacturer of pharmaceutical products.

17.2 The purpose and financing of donations

Donations may only be made where the purpose is to contribute to medical research or improved patient treatment. The donation must be made for a clearly defined purpose. Donations may not be made to the general operation of the Healthcare Organization.

A Member Company cannot demand to be the sole donator and must encourage that contributions are applied for with other sources of financing, including other Member Companies.

17.3 Application and written agreement

Donations may only be given following an application from a Healthcare Organization and Healthcare Professional Association describing the purpose, how the donation is intended used and a budget.

The donation must be stipulated in a written agreement between the Member Company and the Healthcare Organization before it is granted / paid. The agreement must clearly state what the donation comprises, as well as the fee and/or other non-financial contributions.

Both the application and agreement must be signed by the general manager / managing director or any other person with the authority to represent the Healthcare Organization.

17.4 Grants and prizes

Member Companies may however pay for, or contribute to, grants and prizes that will be allocated to individuals where the following conditions are met:

- the selection of the grant or prize winner is made by a committee that has been nominated by a Healthcare Organization and with no opportunity to make proposals or exercise influence upon the Member Company,
- the selection of the grant or prize winner is made based on written criteria (rules),
- the grant or prize is awarded for medical research or patient treatment,
- the grant or prize winner can receive the grant/prize,
- the Member Company pays their contribution into a separate account belonging to the Healthcare Organization and that manages disbursements to grant or prize winners in accordance with prevailing tax and accounting rules,
- the collaboration between the Member Company and Healthcare Organization comes into effect following the application and is stipulated in a written agreement.

17.5 Documentation and transparency

Documentation relating to the donation must be kept by the Member Company for a minimum of five years.

CHAPTER 17 DONATIONS

Subsection 17.1 Donations
Different types of Donations may have different names or criteria in the Member Company's internal regulations e.g., donation, charity, sponsorship, support, educational grant, research grant etc. All Donations given must comply with both the present Rules and relevant internal regulations.

Donations, apart from those to Healthcare Organizations, are not permitted. Hence, it is not permitted, for example, to give donations to individuals.

Regarding support for projects and other financial transfers to Patient Organizations, see Chapter 24.

Highlighting the donator is in accordance with the principle of transparency regarding interaction between industry and partners and is not considered reciprocity according to subsection 17.1, first paragraph.

Subsection 17.2 The purpose and financing of donations
Donations may only be given for the purposes of medical research and/or improved patient treatment. Therefore, donations must always be given with the purpose of benefiting patients and/or the health of the general public.

Donations must be linked to a specific purpose, as described in the application.

"Medical research" means e.g., basic research or clinical research conducted by a Healthcare Organization.

"Improved patient treatment" means e.g. medical training activities, medical training material, development and production of information material, such as brochures, information campaigns, apps and so on. Projects that contribute to expanding knowledge about treatment are also included in the definition.
Donations may take the form of financial contributions or contributions in the form of services, objects – medical resources for conducting a particular project as described in the application.

Subsection 17.3 Application and written agreement
It is very important that the formal rules are followed. It is an absolute condition of a donation being awarded that an application and written agreement as described in this Subsection exist.
The possibility of applying for a Donation should never be employed in a promotional manner by a Member Company.

Subsection 17.4 Grants and prizes
It is not permitted to award Grants and/or prizes earmarked for covering travel and/or accommodation.

Subsection 17.5 Documentation and transparency
Please view chapter regarding transfers of values.

Member Companies publish financial transfers and other contributions that have been made.

CHAPTER 18. PURCHASE OF SERVICES

18.1 About purchasing of services

Member companies may purchase services from Health Organizations, Patient Organizations, Patient Organization Representatives or Healthcare Professionals if the purpose is to contribute to medical research, teaching or better patient care.

There must be a real need for the assignment. The purchase of the services must be based on fair market value. This means that there must be a reasonable match between price and performance.

The assignment must be defined and documented in a written agreement.

18.2 Consultants

Professionals may be used as consultants and advisors, either individually or in groups, for assignments/services such as lecturing, chairing meetings, participating in clinical and other scientific trials, training a company's own personnel, participating on Advisory Boards and participating in market research were this involves remuneration.

Consultants who refer to Medicinal Products, when on an assignment for a Member Company, is subject to the rules of advertisement for Medicinal Products, in, respectively, chapter 6 and 7, even if the assignment, as such, is not considered marketing of Medicinal Products. This includes lectures and presentations that mention the Member Company's products, is considered Advertisement in accordance to these Rules and the Member Company's own procedures, see Chapter 26. The Member Company will, in such scenarios, be responsible to ensure that the lecturer adheres to the advertisement rules.

When using consultants, the following criteria must be met:

a) there should be a legitimately identified need for the assignment/service before a request is made and an agreement is entered,
b) the criteria for the consultant selection should be directly related to the identified need. The persons responsible for the selection must have the necessary competence to assess the extent to which the consultant in question meet those criteria,
c) the number of Healthcare Professionals engaged with the assignment/service should be reasonable in terms of achieving the identified needs,
d) a written agreement should be entered
e) before commencement of the assignment/service,
f) the written agreement should describe in detail the assignment/service and qualification of the size and payment of the compensation,
g) the Member Company must keep a record of the agreements entered,

h) the results of the services, provided/assignments carried out should only be used in accordance with the terms of the agreement entered.

18.3 Healthcare professionals employed in healthcare facilities

Healthcare professionals employed by a Health Trust informs theire employer of the assignment, the nature of the assignment and the agreed remuneration.

CHAPTER 18 PURCHASE OF SERVICES

Subsection 18.1 Purchasing of services
It is against the prohibition on gifts if the fee exceeds a remuneration that is in reasonable proportion to the work

performed, cf. regulation on restrictions on Health Personnel's right to receive a gift, commission, service or other benefit of 29 August 2005 no.941.

Payments must follow the applicable tax and reporting rules.

Any remuneration such as travel expenses, diet and accommodation expenses may be added to the agreed fee.

The industry rules do not regulate how Member Firms can purchase services from other actors, for example communication services from a consultancy firm, digital services or advertising services from private companies etc.

Subsection 18.2 Use of consultants
The Doctor's Associations ethical rules chapter II § 5 state "a doctor must not carry out advertising or marketing for drugs or medical consumables. Mentioning of pharmaceuticals in a professional-medical context in articles, lectures etc., without profit motive, is not to be considered as advertising". It is important that doctors' work for the industry is in line with this. Information doctors give in lecture may be health information, that is, general and objective information about medical issues, including the investigation and treatment of diseases, without it being classified as advertising. If the Member Companies Medicines are mentioned, the lecture must nevertheless be treated as "Advertising" in accordance with these Rules. The written agreements regarding performance of assignments/services, should state that the consultant makes public that he/she is a consultant/adviser for the Member Companies in the performance of the service.

In the same way, Member Companies employees who also practice as Health Care Professionals elsewhere should ensure that the employment relationship with the Member Company is announced when the person concerned makes a public statement on matters related to the employment relationship or to the Member Company in general.

A prerequisite for the payment of fees is a real assignment, it is not permitted to remunerate a consultant for ordinary meeting participation. The total of the remuneration from a company to one consultant should not be of such character that it could influence the consultants' professional integrity.

Please view chapter regarding transfers of values.

CHAPTER 19. ADVISORY BOARDS

19.1 Purpose
The purpose of an Advisory Board is to improve a Member Company's insight into a therapeutic area, scientific data, treatment methods, an unmet medical need or patient experience with that disease/treatment, patient care and other subjects to which the Member Company requires information.

An Advisory Board must only be initiated if there is a genuine need for external expertise and meetings are only organized when necessary.

19.2 Use of external experts
A Member Company can hire external experts as consultants in an Advisory Board. The experts need a written and clearly defines assignment.

External experts are to be chosen based upon professional qualifications, within the area in which they are providing advice, not based on previous, or expected statements, or positions/descriptions in

organizations that might affect decisions regarding the purchase or reimbursement of Medicinal Products.

All Advisory Board meetings must have an agenda showing a clear emphasis on the purpose of the meeting and their expert contributions.

The number of experts attending the meeting, must be purposeful in accordance with the purpose of the meeting.

The number of company representatives present must not exceed more than the required number to ensure completion of the meeting.

19.3 No covert marketing

Advisory Board meetings should not be arenas for (covert) marketing or the prelaunching of new Medicinal Products or indications.

If non-approved indications or Medicinal Products are to be discussed, the meeting should invite, and be chaired by, employees from the Member Company's medical department.

19.4 Execution of meetings

Minutes of meeting must be made.

CHAPTER 19 ADVISORY BOARDS

Subsection 19.1 Definition and purpose

An Advisory Board is an advisory group in which Healthcare Professionals, Patient Organization representative, or other experts give Member Companies advice on health and scientific issues.

General discussion groups, program committees or groups participating in market research are not regarded as Advisory Boards.

An Advisory Board must only be established if there is a genuine need for external competence and should consist only of participants who are able to provide the Member Company with knowledge it does not already possess. In many cases, it will be possible to acquire the same knowledge/insight by other means, in which case an Advisory Board must not be established.

Setting up several Advisory Boards with entirely or partly overlapping purposes is not permitted. The number of meetings must be limited to the minimum required to achieve the actual goal.

FYI Sykehusinnkjøp/Hospital Procurement has its own rules regarding collaboration between doctors in their specialists' groups and the industry.

Subsection 19.2 Using external experts

An Advisory Board's task must be clearly defined and must not consist of providing general advice on a therapeutic area.

An Advisory Board's task should be viewed as a professional assignment, and written agreements describing, for example, renumeration and the task's content must be entered with individual external experts. Work executed for Advisory Boards and similar advisory groups the HCP must get approval by its employer.

At all Advisory Board meetings, the emphasis of the agenda must be on topics in which the external consultants have the opportunity to advise the Member Company.

It needs to be documented why every

expert is requested to participate on the Advisory Board and which unique competence the person possesses.

There should not be more than 6 experts per meeting on domestic Advisory Boards.

There should not be more than 15 experts per meeting on international Advisory Boards.

The number of participants from Member Companies should be maximum half of the number of external experts.

Subsection 19.3 No covert marketing
It is crucial that meetings are called, presented and executed in a manner which does not raise doubt about the exclusive purpose of the meeting being to improve a Member Company's insight into a therapeutic area, scientific data, or other subjects in which gathering of competence is required.

Advisory boards cannot be hosted with the purpose of informing about existing or coming Medicinal Products in the pipeline. Such information can only be disclosed when the discussion requires it. The Member Company must carefully consider how much information is required to share in order to receive professional information from external experts.

Advisory Boards with Patient Organisations Representatives or other, who are not Healthcare Professionals, cannot be hosted with the purpose of informing about prescription-only or nonprescription Medicinal Products. All activities must maintain a high ethical standard, in reference to chapter three.The Member Company must consider whether an Advisory Board with other than Healthcare Professionals is the best way to attract new knowledge.

Regarding prescription-only Medicinal Products, it might be an increased risk that information provided to the Advisory Board is considered prohibited Advertisement. If a Member Company has a genuine need for input connected to prescription-only Medicinal Products from persons who are not Healthcare Professionals, it needs to be carefully considered whether:

1. *It is necessary for contributions from the external experts to provide information about the prescriptiononly Medicinal Products and*
2. *how much information about the prescription-only Medicinal Products is necessary to provide.*

Subsection 19.4 Completion of meetings
It needs to be made written reports following any meeting in Advisory Boards where consultant's contribution appears clearly and with a description of any work done in preparation for or to be followed up after the meeting.

CHAPTER 20. NON-INTERVENTIONAL TRIALS OF MARKET-AUTHORISED MEDICINAL PRODUCTS

A non-interventional trial is a study of a market-authorized Medicinal Product that is prescribed in the usual manner in accordance with the terms of the approved indication. The patient's treatment is not decided in advance by a clinical trial protocol but determined in each individual case based on clinical practice. The prescribing of the Medicinal Product is clearly separated from the decision to include the patient in the trial. The trial

involves no diagnostic or sampling procedures in addition to those carried out in normal clinical practice, and epidemiological methods are used to analyze the collected data.

Prospective non-interventional trials involving the collection of patient data, either from, or on behalf of, Healthcare Professionals or groups of Healthcare Professionals specific to the trial, must follow these criteria:

a) The trial must be carried out with a scientific aim.
b) Requirements regarding written documentation:
   - there must be a written clinical trial plan (protocol), ii) there must be a written agreement between the institution and/or therapist responsible for implementing the trial and the trial's sponsor. The agreement must specify the exercises to be carried out and the basis of any compensation for the work completed (cf. item c).
c) Any compensation paid should reflect a fair market value for the work completed.
d) The trial should be submitted to the regional ethical assessment committee prior to commencement.
e) All rules relating to the protection of personal data must be complied with, including any permits required by the Norwegian Data Protection Authority.
f) The trial must not be carried out with the intention of unduly influencing a decision to recommend, promote the prescribing of, or market or promote the sale of individual Medicinal Products.
g) The protocol must be approved by the Member Company's medical manager responsible for monitoring the execution of the trial.
h) The data must be analyzed within a reasonable time frame. The medical manager is responsible for ensuring that the data is properly archived. The Member Company must send a summarized final test report to all the participating therapists and the regional ethics committee. It must also be made available to the Committee for Information on Medicinal Products upon request.
i) All ongoing trials should be recorded in a publicly accessible database and the trial results should be publicized. If the trial displays results that could affect the Medicinal Product's benefit-risk assessment, the Norwegian Medicines Agency should be informed immediately, and it should be sent a copy of the trial report.
j) The overarching responsibility for the trial lies with the medical manager, who must also ensure that personnel have the requisite training. Any involvement of sales staff must not be connected to the marketing of Medicinal Products.

CHAPTER 21. MEDICAL SAMPLES

21.1 Who can receive samples of Medicinal Products?

Medical samples may only be issued to doctors, dentists, who are qualified to prescribe the Medicinal Product in question to allow them to familiarize themselves with the product.

For prescription-only Medicinal Products, the arrangement only applies regarding products the respective person can prescribe. Samples may be issued only in response to a written and signed requisition from a doctor or dentist.

21.2 Requirements regarding documentation

Member Companies should keep lists of recipients who obtain free medical samples. The lists should be retained for at least two years and be provided to pharmaceutical authorities upon request.

21.3 Quantity restrictions

Only one sample of the smallest packet of each Medicinal Product may be given per recipient per year. If the Medicinal Product exists in different forms or strengths, it may be distributed one sample in each form and strength. The size of the sample must be the smallest packet that is marketed.

21.4 When can medical samples be issued?

It is not permitted to issue medical samples more than two years after a Medicinal Product has been introduced onto the Norwegian market.

The extension of the marketing authorization to cover more strengths or dosage forms for existing indications or for other package sizes (number of units in the package) does not carry an entitlement to issue medicine samples.

21.5 Requirements regarding labelling

Each sample should be labelled: “Free medical sample – not for resale”. Natural medicines should, in accordance with the prevailing regulations, be labelled “natural medicine”.

The sample must be accompanied by a complete SmPC.

21.6 Restrictions regarding prescription status

Samples of Medicinal Products in prescription group A or of Medicinal Products that contain substances that are classified in accordance with international conventions on psychotropic and narcotic substances must not be issued.

Samples of non-approved Medicinal Products must not be issued.

CHAPTER 21 MEDICAL SAMPLES

Subsection 21.3 Quantity restrictions

A year means the 12-month period from when the doctor or dentist in question sends their first written requisition.

Subsection 21.4 When can medical samples be issued?

The introductory date is defined by the Member Company itself and could be the date of the marketing authorization, the date when the product was available or, for example, the date when the new indication was given or introduced onto the market.

CHAPTER 22. MARKET SURVEYS

Market surveys are a means of acquiring knowledge of the marketplace and of preparing promotional and informational activities.

Market surveys should not be carried out for purpose of influencing respondents, communicating promotional messages or encouraging promotional relationships.

Market surveys must not contravene any of LMI’s regulations. This applies whether the Member Company carries out the surveys itself or a third party conducts them on its behalf.

CHAPTER 22 MARKET SURVEYS

The number of respondents must not exceed the number necessary to ensure a good result.

Compensation for participation must not exceed an amount that would be reasonable in relation to the input. When market surveys are carried out amongst health authority employees, the contract should state that the exercise should be cleared with the employer.

Where dialogue takes place with external companies on the purchase of planned or completed market surveys, the Member Company should include the condition that the survey be executed in accordance with these Rules and the prevailing guidelines for remuneration.

Where transfer of values takes place, consider chapter regarding the transfer of values from Member Companies.

CHAPTER 23. TRANSPARENCY REGARDING TRANSFER OF VALUES

23.1 Reporting of Transfer of Values (ToVs)

Member Companies must disclose all direct and indirect transfers of value to Healthcare Professionals, Healthcare Organizations and Healthcare Professional Associations according to this chapter.

Some of the rules apply to Patient organizations, chapter 24.

Definitions in accordance with this chapter:

- Research and development activities are defined as (i) non-clinical studies (defined in OECD Principles on Good Laboratory Practice), (ii) clinical trials (as defined in Directive 2001/20/EC), or (iii) prospective non-interventional studies that involve the collection of patient data from healthcare professionals or at their expense.

This chapter does not apply to ToVs regarding Over the Counter (OTC) - Medicinal Products.

The disclosure obligation does not cover the value of free samples of Medicinal Products (Chapter 21), information and educational material and medical utilities (Chapter 12), meals in a professional context within the approved rates (Chapter 16), as well as the value of ordinary information or promotional material.

23.2 Annual reporting and methods of disclosure

Transfers of values must be reported for one calendar year at a time. Reports regarding last year's figures must be issued within the period of 20th – 30th of June the upcoming year. The reports must be publicly accessible for at least three (3) years from the time the information was made available.

Reporting of transfer of values to HCPs must be made available on Member Companies website. Information about transfer of values to Patient Organizations may be provided on a national or European level. Member Companies are obliged to facilitate LMI creating a link to a common reporting website.

The Member Companies can choose to report the transfers of value in Norwegian or English.

The information will be stored by the Member Company for at least seven (7) years after the expiry of the reporting period.

23.3 National and international reporting

Reporting must be in accordance with the national set of regulations in the country in which the HCP has its primary practice,

principal professional address or place of incorporation.

If the recipient has its primary place of work in a European country other than Norway, and the Member Company does not have the opportunity to submit the value transfers through the parent company abroad, the Member Company must report the value transfers in accordance with the Norwegian regulations.

23.4 Individual reporting on transfer of values to health organizations and Healthcare Professionals

23.4.1 Content and conditions for individual reporting

The following must be reported:

I. Full name of HCP, place and country of work
II. For Healthcare Organizations: Place of registration
III. Transfer of values related to 24.4.2 or 24.4.3

Reports are to be submitted on EFPIA's standard form.

23.4.2 Individual reporting in respect of a Healthcare Organization

For the transfer of values to a Healthcare Organization, reporting must be conducted on an individual level in the following cases:

a) Donations (Chapter 17)
b) Purchases related to events (Chapter 15), coverage of registration fees, travel and subsistence are submitted as separate items on the form (indirect support)
c) Payment for assignments (Chapter 18). Fees for lectures and coverage of expenses will be stated as two stand- alone items on the form.

23.4.3 Individual reporting on HCPs

Value transfers to HCPs must be made public individually, by the company, unless anything else is stated by law.

For value transfers to HCPs reporting must be on an individual level in the following cases:

a) Donation/grants for expenses related to an event such as registration fees, travel and subsistence to be stated as separate items in the form (indirect support)
b) Payment for consultancy (Chapter 19, 20) not covered by the aggregate reporting regulation. A fee for assignments and coverage of travel and accommodation fees are to be submitted as two independent items on the form.

23.5 Aggregate disclosure of transfer of values to Health organizations and HCPs

Transfers of value related to research and development as defined in subsection 23.1 should be reported at aggregate level.

Aggregate information may be submitted for the number of recipients in absolute terms and as a percentage of the total number of recipients and the aggregate amount not submitted individually is to be stated. When value transfers are made indirectly to private recipients through an organization, they must only be submitted once.

All disclosures must be submitted on EFPIA's standard form.

23.6 Disclosure of contributions to Patient Organizations

All Member Companies must annually disclose a list containing all Patient Organizations to which they provide financial and significant non-financial contributions.

For reporting, disclosure and retention requirements, the rules in subsection 23.2 applies when applicable.

The reporting must also include a short description highlighting the contribution, making it easy to understand the significance. The description must also

include the name of the Patient Organization.

For project support, the following must be disclosed:

- The total cost.
- For significant, non-financial contributions, it must appear clearly which use the Patient Organization received.

For assignments, the following must be disclosed:

- The total fee paid to each Patient Organization in the period of reporting.

The written agreements with Patient Organizations must include a clause stating the disclosure of services conducted by the Member Company.

The above is not applicable to confidential information.

23.7 Methodology

Member Companies must publish a summary of the methods they have used to submit the amounts.

For disclosure of value transfers to Health organizations or HCPs, the report needs to describe to which category the transfers were made and in which format in which they are disclosed. As an example, mva and other tax related information, currency exchange effects as well as other information that might affect the scope of the fees.

For reporting of contributions to Patient Organizations, the Member Company must disclose the methods that was used when publishing and identifying transfer to Patient Organizations.

CHAPTER 23 TRANSPARENCY REGARDING TRANSFER OF VALUES

Subsection 23.1 Referral to EFPIA's regulations and the applicability of rules

The duty of disclosure applies in principle to all Member Companies. There are some limited exceptions. For further information, contact the Committee's secretariat.

Transfers relating to prescription Medicinal Products (medication in groups must be reported. Transfers only related to OTC should not be reported. For value transfers regarding products that fall both within and outside the distribution (e.g., a presentation that deals with both diagnostic products and prescription Medicinal Products), the disclosure requirements stated in the regulations must be adhered to.

According to a natural interpretation of the wording, an "indirect transfer of value" is a transfer that is not made directly to, but which nevertheless benefits an identifiable receiver.

The typical case here would be a company that is not an HCO, but is owned by an HCP. Transfers to HCO are published on HCO anyway.

Indirect transfer of values refers to transfers made via a third party that is a professional congress organizer etc. The event may be arranged with or without the industry. If possible, these transfers should be reported individually. If the member company is unfamiliar with the individual recipients, the Tova should be reported in the name of the event organizer that receives the transfers.

Transfer to a Healthcare Organization will also be considered a direct transfer to same, even though the funds may be used to hire Healthcare Professionals as e.g., speakers. This is conditional upon the Member Company having no influence on how the money is spent.

Subsection 23.2 Annual reporting and approaches for disclosure

A Member Company may sign an agreement with a HCP to give a presentation at the end of the calendar year, and that the invoice is paid in the following year. In this case the Member Company must apply current accounting principles to decide how such situations are dealt with and when reporting takes place. However, it must not result in nondisclosure of value transfers, e.g., as a result of principles changing from one year to the next. Information on how to deal with this should be provided in the methodology note, cf. item 23.7.

The disclosure obligation applies to value transfers that the Member Company makes, not to the income/benefit to the recipient. If the Member Company participates in e.g., co-marketing or collaborative marketing, the company discloses the transfers of values it makes itself.

If a third party represents or acts on behalf of a Member Company, the Member Company must ensure that its obligations are fulfilled by the third party. The Member Company is recommended to make written agreements with a third party regarding how obligations contained in this chapter are to be fulfilled. The disclosure is made by the Member Company.

All value transfers to a recipient must be disclosed together and in one place.

Where published in Norwegian it is encouraged to publish in English.

Subsection 23.3 National and international reporting

Value transfers to HCPs, Healthcare Organizations and Patients Organizations, with their registered address in in Europe, must be disclosed in accordance with the national regulations in the country where the recipient has their main practice, regardless of whether the value transfer takes place in Norway or not. This means that it will be necessary to have knowledge of the regulations of other countries e.g., in the event of commissions concerning recipients who have their main practice in countries other than Norway.

The main rule is that the publication is carried out by the subsidiary in the country where the recipient has its main practice/place of registration. If the company has no subsidiary, a website is created in line with the rules in the country where the recipient has its main practice/place of registration. In the case of several company organizations in the same country, the company itself decides which legal entity is most relevant for the disclosures.

23.4 Individual reporting on value transfers to Health Organizations and Health Personnel

23.4.1 Content and prerequisites for individual reporting

Healthcare organization or healthcare professional?

Member companies should describe how the company categorises transfers of value to sole proprietorships (ENK) in the methodology note. Depending on the recipient of the transfer of value, LMI recommends following these disclosure principles:

• Transfers of value to sole proprietorships must be published under Healthcare professionals, unless it would be technically difficult to carry out for the member company.
• Value transfers that go to companies (e.g. AS or ANS) owned by one or more persons must be published under the name of the Health Organisation.

Section 23.4.2 Individual reporting when transferred to the Health Organization and Healthcare Professional Association
Both direct and indirect transfers of value to health organizations must be made public. Where the value transfer goes to, for example, a congress organizer (who assists the Health Organization with the practical organization of supported activity), it must be made public in the following ways:
• The values are published under the name of the health organization (you can put the name of the congress organizer in brackets); or
• The values are published under congress organizer (in these cases, the name of the Health Organization that benefits from the value must be published in brackets).

Subsection 23.4.3 Individual reporting about HCPs
For HCPs employed in a healthcare enterprise the rules in Chapter 15 apply, and therefore the alternatives in a) regarding support for expenses in connection with events, such as registration fees and travel and subsistence, will not be relevant. Letter a) can however be made to apply to private practice general practitioners, for example. The Member Company can further account for this type of value transfer in their methodology note.

Value transfers to HCPs must be disclosed individually.

Privacy laws, which might vary depending on each country, will decide whether complete information can be disclosed. HCP-number and social security number must not be disclosed in Norway.

Based on assessments from the Norwegian Data Protection Agency, as well as basis considerations upon an agreement with the Norwegian Doctors' Association, it is expected that the foundation for treating privacy information about HCPs (such as gathering, storing and publishing privacy information) related to value transfers is deemed justified. Please see the Norwegian Privacy Act paragraph 1 (GDPR article 6 nr 1 letter f.). Basically, consent will not be gathered for this purpose.

Member Companies have a legitimate interest in the disclosure of ToVs. Hence, the treatment of the privacy information, including the disclosure of the value transfers to HCPs are required. In that regard, please refer to assessments providing the cause, from EFPIA's rules and demand about disclosure as well as the Norwegian Parliament's ruling on an issue on this matter in 2019. Meanwhile, the HCPs potential desire to remain confidential or their basic rights are not weighed more heavily than the legitimate interest to disclose the information.

In particular circumstances, the HCPs objection against the disclosure can be sustained. In that regard, please see the terms following the GDPR article 21.Should those circumstances apply, the value transfer needs to be aggregately reported. However, any HCP, must, upon contract agreement that includes value transfers with a Member Company, be informed that the information will be disclosed. As such, the foundation upon which to protest following the cooperation is limited.

The Member Company must incorporate the new legal basis in internal privacy documents and procedures. HCPs must, according to the legislation, be informed about their rights. Please see GDPR art. 13.

Information regarding treatment of privacy information must be handled in the following manner:

- *Incorporated in agreements when interaction between HCPs and industry*
- *Incorporate in invitations from the industry that all interactions require disclosure of value transfers*
- *Information on the company's website*
- *Publicly available information in Norwegian or English.*

The information must appear in all relevant correspondence with HCPs.

Additionally, it needs to be informed that the privacy information will remain public for three years and kept on record by the company for seven years. The longevity of the disclosures and for storing the information is essential for the legal basis.

When informing HCPs, the following template can be used:
"The company will disclose information about value transfers (fee for assignments included related travel and time compensation, cover of travel cost/accommodation and more) that you receive from the company in the country to which you reside and work, in accordance with the EFPIA rules and domestic industry rules.

The information will, as a main rule, be disclosed based on the legal basis of legitimate interest.

The disclosed information will contain the recipient's name, employer, as well as the year of the transfer of value, the type and the value of the transfer that is received from the company. Social security number and HCP- number will not be disclosed. The disclosure will be published on the company's website, as well as through a joint gateway administered by the domestic pharmaceutical association.
The disclosed information will take all general privacy requirements into consideration, as well as common interest of the public including patients, the healthcare service, the industry and the healthcare professionals by:

- *Ensuring the public's trust to HCPs' integrity and independence*
- *Ensure public health through raising awareness about of HCPs' responsibility and decision-making that affects the treatment of patients.*
- *Show dedication to continuous learning and education and updating HCPs, which, ultimately ensures better patient care.*

Subsection 23.5 Aggregated reporting about Health organizations and HCPs

Reporting of non-interventional studies
The provision stipulates that only prospective non-interventional studies fall under the category of research and development (as defined in subsection 23.1), while retrospective noninterventional studies should be reported individually.

In cases where it is not possible to determine whether a study is retrospective or prospective, disclosure should be at individual level.

Otherwise, reference is made to the general terms for individual reporting.

Examples of prospective non-interventional studies:

- *Prospective cohort studies in which the prescription of the medicine is independent from the inclusion of the patient in the study.*
- *A retrospective study to which a prospective element is subsequently introduced.*
- *Long-term extension studies with patient follow up beyond trial specified time for observation and active collection of additional data.*

Examples of retrospective noninterventional studies:

- *Purely observational database review and/or research.*
- *Retrospective review of data in which all events of significance have already taken place.*
- *Studies in which the prescriber later becomes an investigator, but prescribing has already occurred.*

In this context, a distinction is made between the two types of non-interventional studies because only prospective non-interventional studies involving the collection of patient data from HCPs or at their expense should be reported at aggregate level. All other noninterventional studies should be reported individually.

Subsection 23.6 Disclosure of contributions to Patient Organizations
The rules apply to all types of transfers, including purchase of stands and advertisement etc.
All agreements about contributions needs to be publicly available, to avoid the misconception of unfortunate connections between industry, patients and user organizations.
Form for publication of ToVs to Patient Organizations (voluntary) is available on Digitalis.

Subsection 23.7 Methodology note
Each Member Company must prepare a methodology note explaining how the firm has gathered their information. It may be made a joint note that describes principles for disclosure of transfer of values or contributions to Health Organizations, as well as HCPs and Patient Organizations, or it may be made two separate notes attached to the different reports. The note must be available, together with the disclosure form. The note should include information on how the company manages its data.

Examples of what may be relevant to include are:

- *Calculation methods for amounts.*
- *Description of how sensitive information is managed.*
- *Description of how transfers of value across national borders are disclosed.*
- *Threshold for what is provided,*

etc. (the distinction between nonprescription/prescription medicines or types of HCPs/health organization).
- *How contracts that run over several years are managed. Other relevant information relating to the disclosure.*
- *How non-interventional studies are reported.*
- *What indirect transfers of value to a third party other than HCPs and health organizations are reported.*

The list is not exhaustive. The Member Company is responsible for the content of the methodology note.

CHAPTER 24. CONTACT WITH PATIENT ORGANISATIONS

24.1 Principles for collaboration

When collaborating with Patient Organizations the following is required:

- Patient Organizations must maintain its independence. When collaborating with the pharmaceutical industry, the pharmaceutical industry must not influence the professional or political stance of the Patient Organizations.

- All collaboration with Patient Organizations must be based upon mutual respect. Each party's perception and decisions must be of equal significance and importance.

- A Member Company must not collaborate with a Patient Organization with the intention to unduly promote sale, use or promotion of a particular Medicinal Product.

- The purpose of the collaboration must be publicly available. Both financial and non- financial support must clearly appear.

- Member Companies must encourage Patient Organizations to seek multiple sources of income.

24.2 Prohibited marketing

It is not permitted to advertise for prescription-only Medicinal Product/Products to anyone but Healthcare Professionals, reference subsection 7.1. The responsibility to ensure cohesion, including material that is distributed, to Patient Organizations are in accordance with the advertising rules, lies solely on the Member Ccompany and their advertisement manager, ref. subsection 26.1

24.3 Rules for collaboration with Patient Organizations

24.3.1 Purpose

A Member Company may collaborate with a Patient Organization to support their work, including assisting with information to the general public, patients and relatives, as well as utilize their expertise.

24.3.2 Collaboration projects

Patient Organizations and Member Companies may collaborate on patientoriented projects. It must be organized as a separate project with a budget and set down in a written agreement that describes the project, including the fair market value of the parties' efforts.

A written agreement must be signed by both parties prior to start up.

It is a condition that both parties contribute to the project. The distribution of effort must reflect that both parties are to be considered equal partners. The Patient Organization's contribution in a collaborative project may be hourly work effort, which must be calculated

according to fair market value.

In connection with the agreed project, the Member Company may make a financial contribution to the secretariat function of a Patient Organization but shall not take over the practical administration of this.

24.3.3 Advertising and stand purchases
A Member Company may buy advertisements in the Patient Organization's journals or websites. A Member Company may also buy stands/advertisement space at the Patient Organization's events in line with chapter 14.2.

The purchase must be at market price and take place in such a way that neither society nor the organization's members can call into question the independence or integrity of the Patient Organization(s) and the Member Company(s).

24.3.4 Other cooperation
A member company may enter into ordinary membership, as well as subscribe to the member's magazine. Furthermore, Member Companies may enter into agreements with Patient Organizations in accordance with Chapters 18 and 19.

24.3.5 Exclusivity agreements are not permitted
A Member Company shall not claim to be the only partner in a significant project under the auspices of a Patient Organization.

24.4 Income limitation
The total income from the pharmaceutical industry must not exceed 15% of the Patient Organization's annual budget.

For Patient Organizations with limited turnover, the total income from the pharmaceutical industry must not exceed 40% of the annual budget. Limited turnover means Patient Organizations with a budget of less than NOK 250,000 per year.

24.5 Use of logos or other material belonging to the parties
A Member Companies public use of a Patient Organization's logo or other material requires written permission from the Patient Organization. When applying for permission, it must be clearly stated about the purpose and in which way the logo and/or material is to be used.

Logos/material must not be used in such a way as to create perceptions of dependence between the Patient Organization and the Member Company.

CHAPTER 24. CONTACT WITH PATIENT ORGANIZATIONS

Employees in the pharmaceutical industry, must not have honorary posts in a Patient Organization, unless it is obvious that there are no unfortunate connections.

Member Companies must not affect text or other material coming from the Patient Organization in such manner that it favors own commercial interest. This will not however, prevent Member Companies from correcting actual errors.

Patient Organizations may ask for company input or text drafts from an open and scientific perspective.
Section 24.4 Income limitation
All income must be calculated, ad purchases etc. included.

A clause regarding income limitation from the industry should be incorporate into agreements between Member Companies and Patient Organizations.

CHAPTER 25. MEMBER COMPANY EMPLOYEES

25.1 Employees

The Rules in this chapter apply to all employees of Member Companies.

The Rules also encompass employees in other companies connected to the Member Company (e.g., in Nordic sister companies) as well as contractors and consultants when they perform the identified jobs/functions on behalf of the Member Company.

25.2 Medical Sales Representatives

A medical sales representative is an employee of a Member Company whose job function includes external sales and marketing activities directed toward Healthcare Professionals.

25.3 Registering of Medical Sales Representatives

A medical sales representative should be registered with LMI in accordance with the prescribed provisions.

There is a separate procedure for the registering of consultants who work only towards pharmacies with non-prescription drugs.

There is an annual registration fee.

25.4 Medical sales representative activities

Medical sales representatives must perform their duties ethically and responsibly.

Medical sales representatives must immediately notify their Member Company of all information they may receive in relation to the use of the Medicinal Products they are presenting, particularly information about side effects.

Medical sales representatives must ensure that the frequency, timing and length of their visits to Healthcare Professionals, pharmacies and hospitals, or other places where Healthcare Professionals may be employed, or their nature or content, do not create problems for or inconvenience those who they are visiting.

Medical sales representatives must never consciously conceal their identity or that of the Member Company they represent when contacting Healthcare Professionals.

25.5 Training of employees

Medical Sales Representatives

Training of medical sales representatives

Medical sales representatives should be provided with adequate training by, or on behalf of, the Member Company they are employed by, and should have adequate professional knowledge to enable them to present information about the Member Company's products in an accurate and responsible manner.

Member companies must ensure that the sales rep has basic medical and pharmaceutical knowledge.

Sales reps must have passed the Act and Sector Course organized by LMI.

Other employees than sales representatives

The requirement to complete and pass the exam on the Act and Sector Course, also applies to employees other than medical sales representatives, whose external activities primarily focus on information about Medicinal Products directed toward Healthcare Professionals (e.g., medical advisors), and Market Access professionals with external customer contact.

Deadline

The deadline for completing the necessary training and exam is 12 months after employment in a position covered by the training requirements set out in the present subsection.

25.6 Requirement for e-learning course

25.6.1 LMI's E-learning course

LMI's E-learning course aims to reinforce

knowledge of the advertising rules across the whole Member Company organization. The course ends with a final test, following distribution of certificates.

LMI may charge a fee for completing the course. See the guide for additional information.

25.6.2 Employee groups
Generally, LMI's E-learning course is mandatory for anyone who encounters customers.

This normally includes the following employees:

- Managing Director/Administrative Director/Country Manager
- Marketing Manager/Director
- Sales Manager/Director
- Product Manager
- Product Specialist
- District Sales Manager
- Medical sales representative
- Medical Manager/Director
- Medical Advisor
- Compliance Officer
- Clinical Research Associates
- Registration Manager and registration employees
- Information Manager/Director
- Marketing Co-Ordinator
- Information employees
- Market access employees and managers
- Others having event, product or customer responsibilities

List of employees who are not normally required to take the course (for example):

- HR managers and employees
- Factory directors/managers, production employees or technicians
- Catering employees
- Secretarial/office employees who perform only work internal to the company
- Accountancy employees

There is an attached condition that these employees do not have responsibilities relating to events, products or customers.

25.6.3 Deadline
New employees must complete the course before their first unsupervised customer contact and within three months after being hired.

The course is mandatory for all employees. In the event of major revisions the course must be retaken.

The course is to be completed within six months of such notification having been issued.

25.7 Overview of employees
Upon request from LMI, Member Companies containing relevant information about training of the individual regarding the Regulations.

The Member Companies are responsible to ensure that employees to whom the course is mandatory, completes it on time.

CHAPTER 25 MEMBER COMPANY EMPLOYEES

Subsection 25.2 Medical Sales Representatives
Medical sales representatives may have different titles in different companies e.g., product specialist, "Account Manager" and so on.

Subsection 25.3 Registering of Medical Sales Representatives
Medical sales representatives will be issued with membership certificates upon registration. The membership certificate must be displayed upon request; therefore, medical sales representatives must always carry them when they are acting in this capacity.

The annual registration fee is currently NOK 1,000.

Subsection 25.5 Training of employees
Completion of the Act and Sector Course and passing the examination are mandatory for medical sales representatives and for everyone who has external activities toward Healthcare Professionals as part of their work assignments, e.g., medical advisors.

Employees other than medical sales representatives who have more than five years of experience from the pharmaceutical industry may choose not to attend the introduction section of the course.

Subsection 25.6.1 LMI's e-learning course
LMI presents information regarding the participation fee for the e-learning course per employee on Digitalis. The fee is invoiced to the Member Company.

Subsection 25.6.3 Deadline
The requirement for "new employees" does not apply where the new employee has already completed the course (for example, with a previous employer) and not sufficiently long ago as to require mandatory repetition of the course.

Subsection 25.7 Overview of employees
It is the Member Companies' responsibility to ensure that the lists submitted upon request to LMI are updated and contain correct information.

CHAPTER 26. ORGANISATION AND APPROVALS

26.1 Responsibility for Member Company Advertising

Every Member Company must set up a scientific service to oversee the company's Advertising.

Member Companies must implement procedures for the approval of material and activities to ensure compliance with the Industry Rules and relevant statutory acts and regulations.

A person responsible for authorizing all advertising material prior to publication must be appointed. The appointee must be a doctor or pharmacist (MSc in Pharmaceutical Sciences). An application for approval of these qualifications must be approved by LMI. The Member Companies must report the name, qualification and job title of the responsible person to the Committee secretariat.

26.2 Approval of Advertising

Advertising copy must not be used before the final version has been reviewed and authorized by the Member Company's scientific service. The person authorizing advertising material cannot oversee its design.

Advertising material that is continuously used, should be re-authorized at previously specified intervals to ensure that the information is up to date and in accordance with the prevailing regulations. The intervals should be approved as part of the first authorization of the Promotional material.

26.3 Other approvals

In addition to Advertising, all other material used for providing information about health, disease or the company's Medicinal Products should be approved in accordance with subsection 26.2 before it is used.

This includes, but is not limited to:

- Information or training material that is not-Promotional materials
- Disease awareness
- Press releases which mention Medicinal Products
- Material that will be used in collaborative work with Patient Organizations

26.4 Internal monitoring

Member Companies should have a system for internal monitoring which keeps a summary of all professional and nonprofessional meeting agendas and an itemization of the subject matter. Internal monitoring documentation should be retained by the Member Company for at least two years. The Committee's Secretariat may request access to the documentation.

26.5 Archives

Member Companies should make sure that all authorizations are kept together with the final version of approved material for at least three years.

26.6 Promotional materials uploads

Prior to launch, Member Companies are obliged to submit copies of all Promotional materials, regardless of the format used by the business, to the electronic archive administered by the Committee's Secretariat.

Member Companies must submit an overview of their websites, social media accounts, channels etc. twice a year.

The Secretariat requests payment for each submission. Refer to the guidance for current rates.

CHAPTER 26 ORGANISATION AND APPROVALS

Subsection 26.1 Responsibility for Member Company Advertisement

The EFPIA code states that scientific service must include a medical doctor or, where appropriate, a pharmacist who will be responsible for approving any promotional material before release.

The person responsible, may delegate approval of advertisement and other material to other employees within the Member Company, despite the person not having the same education, but possess relevant competence.

Subsection 26.6 Promotional materials should be sent to the Committee's Secretariat

FYI The rules for approval and submissions differ. Non-commercial content must be approved, but not submitted to the e-archive.

Duty to submit

The duty to submit copies of all Promotional materials, regardless of their format, to the Secretariat's electronic archive applies to all those holding marketing authorizations for Medicinal Products, including those who are not members of LMI. This is due to the fact that the LMI administers the archive on behalf of the Norwegian Medicines Agency.

Examples of material

Examples of documents that are considered as advertising:

- *Advertisements, announcements, direct mail, inserts, brochures and other kinds of advertising material*
- *Promotional films*
- *Invitations to Advertising meetings*
- *Presentations and other material shown at Advertising meetings,*

including any shown by an external speaker
- *Reprints of scientific publications used in advertising context*

(This list is not exhaustive)

<u>Examples of documents that are not considered as advertising:</u>
- *Material connected to clinical investigations*
- *Information given to doctors in response to direct enquiries*
- *Reprints of scientific publications, treatment guidelines and other reference material that are not used on an advertising context*
- *Other material that is not Advertising (e.g., technical guidance, health and disease awareness, press releases and stock exchange announcements)*
- *Participant lists*
- *Agreements*
- *Invitations to and agendas of, Advisory Board meetings*
- *Text for the Pharmaceutical Product Compendium*

  (Felleskatalogen), even if it is for Advertising

(This list is not exhaustive)

<u>Electronic submission</u>
Submissions are made electronically by uploading documents to the company's account in the Secretariat's electronic archive.

A good directory structure is desirable so that information can be retrieved easily. Presentations which belong to the same meeting should be kept together.

Advertising material (i.e., videos, brochures and presentations) published on Member Companies websites must be uploaded priori to use.

When using external speakers, where it is not possible to obtain the lecture before it is held, the lecture should be submitted as soon as possible afterwards.

It is unnecessary to upload material when reused in other formats (i.e. brochures that are converted from paper to a digital document) where the content is the same. If the visual expression is changed, word removed or added, the content is considered changed and must be uploaded.

<u>Uploads of Member Companies webpages/websites</u>
Uploads are being made by April 1st and October 1st.

A Member Company uploads links directly into the electronic archive (i.e., in a word document containing a list of all links). The links are uploaded in folders underneath the main folder and can be called "Links April 1st XX" and "links October 1st XX".

Member Companies must upload links to all Company websites/webpages where advertising of their pharmaceuticals is to be found. This does not apply to websites owned by a third party (i.e., www.dagensmedisin.no etc. Advertising on these sites is uploaded as usual.

Company websites that are relatively static and where the key message is to be found in the e-archive, a link to the site is as a main rule sufficient.

Temporary websites (i.e., regarding an advertising campaign) where twice a year upload is considered insufficient

for review/supervision, must be uploaded with screenshots.

Fees
As of 01.01. 2017 there is a fee per documents submitted by Member Companies. LMI will inform members of the size of the fee via Digitalis.

The price is per document so if, for example, ten documents connected to a meeting are uploaded to one folder, the price due will be for ten documents.

The Committee's Secretariat (LMI) will invoice Member Companies in arrears once a year.

Access to the archive
Every single company can only access their own account.

One user will be set up for each company once that company has responded with details of to whom that user should be. When the employee with access to the electronic archive leaves the company, it is important to notify lmi@lmi.no so that the user and password can be deleted. At the same time, notice should be given of who will be taking over the responsibility so that the new user can be set up.

Members of LMI who, in their capacity as consultants, upload material on behalf of other companies should place such information in that company's directory rather than in their own area of the electronic archive.

The Norwegian Medicine's Agency and the Committee's Secretariat have access to the whole of the archive and will carry out checks (systematic checks and/or spot checks) in order to verify that a company's Advertising conforms to the prevailing regulations.

The material will be available in electronic archives for at least two years.

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