The Association of the Pharmaceutical Industry

2020

EDITED VERSION AUGUST 2020

WITH GUIDANCE 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 MAY 26, 2020 AND CAME INTO FORCE ON JUNE 1, 2020

In the period from June 1, 2020 to September 1, 2020, 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.

Foreword by LMI's managing director

The Association of the Pharmaceutical Industry in Norway bases its activity on expertise, professionalism, transparency and integrity for the good of patients. Our main tasks are to develop new and effective medicinal products and to improve existing treatment regimes, As well as to make these available and known in such a way that they are beneficial to the individual patient.

The Association of the Pharmaceutical Industry in Norway has significant expertise regarding medicinal products, health and disease. By providing information and sharing our knowledge, we contribute to correct medicinal use and thereby to improved health. Our concern is to ensure that the right patient gets the right medicinal product at the right time. Those making decisions about the patient's treatment require access to good information in order to achieve this. This is especially important in the choice of treatment, both in deciding between non-medicinal and medicinal treatment and when choosing between the different medicinal products available.

Public authorities finance the bulk of medicinal purchases in Norway including the national insurance scheme and the operation of hospitals. Through their choices, particularly in an everyday clinical setting, doctors administer large sums of money on society's behalf. This places great demands for cooperation between doctors and other health personnel and the pharmaceutical industry. Our desire is to contribute to creating an environment where decision-makers, patients and the society as a whole, considers the pharmaceutical industry as a trustworthy and credible partner, that centers around respect, integrity, openness and the patients.

Detailed rules managing and placing limitations on how member companies may interact with health professionals and for transparency requirements, contribute to society's confidence in the medicinal product industry. The pharmaceutical industry works vigorously to research and develop new, innovative treatments and products to cover today's as well as tomorrow's requirements. We are proud of what we achieve; that we contribute to improve and save lives, every day.

Managing Director
Karita Bekkemellem

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, 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 29 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

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PART I
INTRODUCTION

CHAPTER 1. DEFINITIONS

Defined words have initial capitals.

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 having special expertise in the relevant technical field which 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 Organisations: Healthcare organisations 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, or (iv) which is an association of health professionals (see item 1.5).

1.5 Healthcare Professionals: Healthcare Professionals means doctors, dentists, veterinary surgeons, aqua medicine biologists, authorised nurses, pharmacists, opticians and dental hygienists as well students in the related subjects.

1.6 Healthcare Professional Association: Healthcare Professional Association means a non-commercial organisation of Health-care Professionals having a common interest, subject or discipline they wish to promote.

1.7 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 which affects physiological functions in people or animals or which may be applied or given to people or animals to restore, modify or affect physiological functions through a pharmacological, immunological or metabolic effect, or to detect disease.

1.8 Pharmaceutical samples
A pharmaceutical sample, is the smallest pharmaceutical package available for distribution to healthcare professionals according to chapter 24. The purpose of such distribution, is to ensure that health-care professionals can familiarise them-selves with the prodict.

1.9 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.

1.10 Patient-User Organisation: Patient-User Organisation means a non-commercial interest organisation for disabled and chronically ill persons and/or their families and other interested members of the general public.

1.11 "*Preparatomtale*": "*Preparatomtale*" means authorised SmPC; see definition in subsection 1.16.

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 for humans and animals.

1.14 Advertising Meeting: Advertising Meeting means a meeting of Healthcare Professionals arranged by a Member Company during which information on specific Medicinal Products is imparted with the intention of promoting sales or use/application.

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.

1.15 Patient- User Organisation 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- User Organisation.

1.16 SmPC: SmPC means Summary of Product Characteristics which are *Preparatomtale* approved by the Norwegian Medicines Agency as part of the marketing authorisation 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 Organisations
The requirement for a Healthcare Organisation to be a "legal entity" means that it must have an organisation number.

Examples of forms a Healthcare Organisation can take are a health trust, a private clinic or the Faculty of Medicine at the University of Oslo.

Subsection 1.5 Healthcare Professionals
There are various definitions of the term healthcare professional existing in the Norwegian legislation. The definition, in subsection 1.3 used in these Rules, is taken from Section 13.1 of the Norwegian Regulations relating to Medicinal Products (legemiddelforskriften).

It should be noted that Act No. 64 of 2 July 1999 relating to Healthcare Professionals (the Healthcare Professionals Act), has a broader definition than Section 13.1 of the legemiddelforskriften. Many occupational groups (in the broader sense) such as pharmacy technicians, psychologists, physiotherapists, clinical dieticians etc. are classified as healthcare professionals under the Health Personnel Act. In the legemiddelforskriften however, they are called "other healthcare professionals" and not Healthcare professionals (in the narrow sense) as stated under Section 13.1 in the and 1.5 in this code. The group "other healthcare professional" are unable to receive Promotional materials for prescription Medicinal Products.

*The broad group of healthcare professionals, so called "other healthcare professionals", may however participate in **interdisciplinary** meetings with advertising for prescription drugs provided that (i) Healthcare Professionals in the narrow sense (as mentioned in legemiddelforskriften and 1.5 in this code) participates, and (ii) that their employer **assesses** that there is a **professional need for their participation**.*

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

Subsection 1.6 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 Organisation.

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 salesactivities, including all electronic and printed material used by them*
- *Distribution of medical samples*
- *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 authorisation*
- *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 health or disease information.*
- *Press releases (see Chapter 11)*
- *Non-interventional trials (see Chapter 23)*
- *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 authorisation (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 organisations, for example, health authorities, the Norwegian Institute of Public Health (Folkehelseinstituttet) or the Norwegian Hospitals Procurement Service (Sykehusinnkjøp HF, previously known as HINAS/LIS) are not considered Promotional materials. Tenders submitted in advance of receiving "Positive Opinion"/marketing authorisation 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 Organisations, 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) Any product information must be kept to a minimum
c) 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)
d) All information must be plain, factual and objective, and must not appear promotional
e) Information must be based principally on facts in the form of financial information, technical information, information from authorised 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.

Answers to specific enquiries
Correspondence, possibly including any plainly designed material of a non-marketing nature, that is needed for answering specific, unsolicited questions about a particular Medicinal Product is not regarded as "Advertising".

Conveying information might also be permitted when answering specific and unapproached questions from healthcare professionals.

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 non-specific 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.

Pharmaceutical development/pipeline specifics

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 Authorisation 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 Authorisation 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 approved pharmaceutical is provided*

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, 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.

One example: In the main program at a third-party congress, can phaseIII results regarding a Member Company product X, be presented. The same data cannot, however, be presented at the Member Company's symposium or be visualised at their stand at the same congress, as this would be considered Advertisement, and subsequently prohibited prior to launch.

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 authorisation 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 and not from employees working in a specific area (this also applies to employees in a Member Company's medical department).

Any hints, such as use of layout and graphical elements in Promotional materials or invitations suggesting associations with specific future Medicinal Products, are not allowed.

Remember that the ban applies to "Advertising"; in other words, direct or indirect statements about a Medicinal Product with the intention of promoting use/application or sale.

A further practical question concerns the extent to which it is permitted for a Member Company to be engaged in company profiling within a therapeutic area where the company has no Medicinal Products with marketing authorisation and approved price, for example, where marketing authorisation is expected to be given in six months' time. It could be useful for a Member Company to become familiar with a therapeutic area and, for example, have a company stand at a congress within that therapeutic area. This may be permitted on the precondition that specific future Medicinal Products are not discussed in a promotional context. Neither is it permissible to behave in such a way as to "trigger" or pave the way for questions about a non-approved Medicinal Product. Companies must, in such cases, be particularly careful not to behave in such a way that leads to the activity being seen as marketing, which would be regarded as illegal pre-launching.

Subsection 1.14 Advertising Meeting
By the term other healthcare professionals, means healthcare professionals as stated in the Healthcare Professionals Act (helsepersonelloven) section 3. The Healthcare Professionals Act considers, among others, pharmacy technicians, health secretaries, radiographers, clinical nutritionists etc as healthcare professionals.

Subsection 1.16 SmPC
SmPCs for Medicinal Products with marketing authorisation in Norway are available on the website of the Norwegian Medicines Agency.

CHAPTER 2. SCOPE OF THE RULES

2.1. Human Medicines
The Rules only apply for Advertising for and activity connected with Medicinal Products for human consumption.

For activities relating to veterinary Medicinal Products, refer to the rules for the marketing of veterinary Medicinal Products.

2.2 Legal status for supply
The Rules apply to Advertising for 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.

2.3 Geographical scope
The Rules apply in Norway. "Norway" means the Norwegian mainland, Jan Mayen, Bjørnøya and Svalbard.

Unless otherwise apparent from the context, the Rules also apply outside Norway when the Member Company is addressing Norwegian Healthcare Professionals.

2.4 To whom do the Rules apply?
The Rules apply to all Member Companies and their interactions with Healthcare Professionals, Health Organisations, healthcare professional organisations, Patient- User Organisations and Patient-User Representatives, as well as any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his/her professional activities, may prescribe, purchase, supply, recommend or administer a Medicinal Product.

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

This applies unless other information is explicitly 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.

2.5 Platforms upon which the Rules are practiced

The Rules are applying regardless of platform format; printed, stated, electronic or digital communication.

2.6 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

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 13 or amount restrictions in Chapter 18 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/colour scheme) to be associated.*

Subsection 2.3 Geographical scope

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 general public. The language is not crucial, but if information appears in Norwegian, it will generally be considered to be "aimed at" Norwegian users.

Subsection 2.4 To whom do the Rules apply?

Section 13-7 of the Medicinal Products Regulations (legemiddelforskriften) states who counts as a Healthcare Professional in accordance with the pharmaceutical legislation in Norway. This definition is followed in the industry rules. The scope of the industry's collaboration has been expanded to include a larger group, in line with EFPIA's broad definition of healthcare professional. This means that the industry rules must be followed in Member Company's interaction with this extended group, unless otherwise is explicitly stated in the industry regulations (for example, special rules apply for advertising).

The Member Company must ensure that all employees act in accordance with the regulations, regardless of role or function.

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.

PART II

GENERAL REQUIREMENTS

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.

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 ProductProduct should not be disrespectful.

3.2 Transparency with regard to activities and agreements

Member Companies should ensure transparency regarding activities and agreements entered into with Healthcare Organisations, Healthcare Professionals and Patient-User Organisations, as well as Patient-User Organisations Representatives.

3.3 A Member Company should not give personal advice on medical treatment

A Member 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.

3.4 "Important Notice" and withdrawal of registration

Information relating to new, serious side effects or contraindications, limitations in relation to indications and decisions to withdraw due to side effects must be sent out separately to issuers of prescriptions and pharmacies. The term "Important Notice" [Norwegian: Viktig melding] must be used only for such notifications.

Where it is in the public interest, withdrawals should always be communicated to issuers of prescriptions and pharmacies. All withdrawals should be justified.

CHAPTER 3 HIGH ETHICAL STANDARDS AND TRANSPARENCY

Subsection 3.4 "Important Notice" and withdrawal
The Norwegian Medicines Agency has guidelines on standard marking.

CHAPTER 4. MARKETING AUTHORISATION

4.1 Timing of product marketing

A Medicinal Product must not be marketed before it has been given a marketing authorisation 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 authorisation. 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.

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 8.2 (j)).

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 8.9 below.

CHAPTER 5. DIGITAL CHANNELS, ETC.

5.1 Digital channels/platforms

Digital channels consist of, amongst other, websites, social media and more.

5.2 Specifically regarding the internet

5.2.1 General Information

At all times it must be obvious to the user of a website who the owner of or contributor to a website is and which target group (the

general public or Healthcare Professionals) the website is aimed at.

The landing page on a website intended for both the public and Healthcare Professionals must be suitable for both target groups and may not contain Advertising for prescription-only Medicinal Products. If the website is intended exclusively for Healthcare Professionals, this must be stated clearly in a disclaimer or similar before access is granted to the landing page.

5.2.2 Separate website categories

a) The company's home page
The company's home page must feature a clear division between pages for Healthcare Professionals and for the public. The website must clearly show the cross-over from pages designed for public viewing to those meant for Healthcare Professionals only, before access to these pages is granted.

b) Websites that contain advertising for prescription-only Medicinal Products
A website that contains advertisement for prescription-only Medicinal Products, must be exclusively directed towards Healthcare Professionals. It needs to be clearly marked that the website is meant for Healthcare Professionals prior to entering.

c) Websites containing advertisement for non-prescription Medicinal Products
Websites containing advertisement for non-prescription Medicinal Products, and, that are mainly directed towards the public, might, if clearly separated, link to websites directed towards Healthcare Professionals. However, the website needs to clearly state that it is for Healthcare Professionals prior to entering.

d) Websites that contain information about health and/or diseases, and which are intended primarily for the public
Websites that contain information about health and/or diseases, and which are intended primarily for the public may not contain a separate section/website (nor separate pages) intended for Healthcare Personnel, nor links to pharmaceutical advertisement for prescription-only and non-prescription Medicinal Product. It is permitted to link to other websites/ pages for the public, and to the front page of the company's website or to the page for the public on the company's website.

5.2.3 Advertising for prescription-only Medicinal Products
Advertising for prescription-only Medicinal Products published online and directed towards Norwegian Healthcare Professionals must follow all of the relevant provisions in these Rules. Refer to Chapters 4 and 8 in particular.

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 8.2) can be placed in links provided that the links are obvious and easy to see and that they are direct links (one-click).

Special rules apply for banner advertisements designed as reminder advertisements (see subsection 8.3).

5.2.4 Advertising for non-prescription Medicinal Products
Advertising for non-prescription Medicinal Products published online and directed towards the Norwegian public must follow all of the relevant provisions in these Rules. Refer to Chapters 4 and 7 in particular.

Mandatory information for non-prescription Medicinal Products, cf. Subsection 7.7, must be displayed in the Promotional material itself and cannot be replaced by links to more comprehensive information.

5.2.5 Health and disease awareness
Health and disease awareness published online and directed towards the Norwegian public must follow all of the relevant provisions in these Rules. Refer to Chapter 10 in particular.

5.2.6 SmPC and package inserts
The SmPC and package inserts for prescription Medicinal Products may be made publicly available online provided that they are not presented in a promotional manner.

5.2.7 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.

5.2.8 Reporting to the Committee's Secretariat
Member Companies must send a summary of their own websites, as well any websites/web pages to which they contribute, twice a year to the Committee's Secretariat.

5.3 Electronic and digital communication

When using electronic or digital forms of marketing such as newsletters, emails, apps or similar, mandatory information must be distributed in accordance with the provisions in subsections 5.2.3 or 5.2.4 above, as appropriate.

Marketing communications to physical persons via email or other electronic forms of communication directed towards a single individual are permitted only if the recipient has previously given their consent to receive them.

5.4 Audio-visual communication, including film, DVD and interactive communication

When using audio-visual communication, including film, DVD and interactive communication such as e.g. live streaming, mandatory information must be distributed in accordance with the provisions in subsections 5.2.3 or 5.2.4 above, as appropriate. When communicating with Healthcare Professionals, mandatory information may be shared in a document that is accessible to all viewing, or participating in, the communication, or may be included directly in the audio-visual communication itself. In this case, it must be clearly apparent how the information can be accessed.

5.5 Social media

5.5.1. General information
Social media are media which, with the assistance of the Internet, allow interaction between two or more parties, where people talk, participate, share, create networks and bookmarks on the Internet.

The Member Company's page is an area in social media that the Member Company owns or administrates.

All information published on the Member Company's social media pages must abide by all relevant provisions in the Rules. For Advertising, see in particular Subsections 5.2.3. and 5.2.4.

Member Companies must monitor comments and other 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's posts on others' social media pages – both sponsored content/Promotional materials (paid placement) and ordinary participation in social media (non-paid) – must comply with the Rules.

5.5.2. Information targeted at the public
Unless access to pages set up by Member Companies in social media is technically restricted to Healthcare Personnel, the page shall be considered targeted at the public and may therefore only be used to publish information that may legally be presented to the public. The same requirements apply to posts from the Member Companies placed on others' social media pages.

5.5.3. Control and responsibility for the contents
When using social media, the Member Company must clearly state who is behind the information, including discussions and comments posted on the page, irrespective of who may be the author of the individual posts.

The Member Company must make clear

to users of the Member Company's social media pages, the terms and conditions that apply to comments and to sharing other information on its page. The Member Company must also inform users that messages and comments posted will be monitored.

5.5.4. Personal use of social media

Posts and comments – including shares and "likes" – in social media from the Member Company's employees related to the individual Member Company or its products which can be considered communication from a representative of the Member Company 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 web pages. A website is a domain – for example www.pharmceuticalcompanyname.no, www.theme.no *– and a web page is a page on a website.*

The name, address and email address of the owner or sponsor of the website must be shown.

Subsection 5.2.2 Separate website categories

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 must clearly show the cross-over from pages designed for public viewing to those meant for Healthcare Professionals only. This can be done in various ways, but the transition must be obvious and easy to recognise.

The Rule stating that it is not permitted to link to websites intended exclusively for Healthcare Personnel from websites intended for the public means that it is not permitted to link to a website for a prescription-only Medicinal Product – to www.product.no, for example – from a website intended for the public, e.g. www.health and diseaseinformation.no.

Subsection 5.2.3 Advertising for prescription Medicinal Products

Advertising must always be balanced regarding 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.

The 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.

Specifically concerning banner advertisements for prescription Medicinal Products

Banner advertisements on web pages occupy a limited display area. This means that banner advertisements for prescription Medicinal Products should be designed as reminder advertisements. A reminder advertisement should contain only the Medicinal Product's name and the generic name of the active ingredient together with the marketer's name (cf. subsection 8.3).
A banner advertisement may point to further information about the Medicinal Product by using text such as "If you would like to read more about [product name]" to show that it is possible to proceed further for more information about the product. It must be stated that the page being visited is designed for Healthcare Professionals, either within the Promotional material itself or with a disclaimer, or similar, before the new page opens.

Subsection 5.2.4 Advertising for non-prescription 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 7.7 – in Advertising of non-prescription Medicinal Products on the Internet, the following guidelines apply:

- *Advertising films for non-prescription 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 7.10.*
- *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 smartphone 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 name of the active substance if the product only contains one active substance, in accordance with point 7.6 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 7.6 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/ beast 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 7.7 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 SmPC and package inserts
It follows from the EU court case C-316/09 that the availability of the SmPC or package inserts for a prescription Medicinal Product on a pharmaceutical company's website is not regarded as "Advertising" and therefore should also be accessible by the public, provided that the SmPC or package inserts are made available as they are. No selection, emphasis or redrafting of parts of the text may take place. It is of significance that the SmPC or package inserts should be made available on the website for those looking for information and that the information not be forced upon individuals who do not wish to be informed (pull rather than push).

One method of achieving this in practice is by making the SmPC or package inserts accessible from a neutral overview of the company's products.

Subsection 5.2.8 Reporting to the Committee's Secretariat
The submission of websites to the Committee's Secretariat encompasses all forms of online marketing, including social media such as Facebook. Submissions should include a summary of the domains and social media accounts operated by or at the disposal of the Member Company.

Submissions should be made each year on 1 April and 1 October.

Subsection 5.5 Social media

Subsection 5.5.1. 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.

Social media are considered equal to all other communication channels. All communication conducted by the Member Companies, irrespective of the type of post or the platform on which it is communicated, must remain within the framework set out in these Rules.

The Member Company is responsible for all content which is published on the Member Company's page and targeted at Norwegian users of social media, cf. Subsection 2.3. This responsibility also covers statements from third parties, such as comments from users or the sharing of posts.

This means that the Member Company must have monitoring procedures in place (or a separate pre-approval procedure, where possible) which ensure that the content is at all times in compliance with the Rules, and that the Member Company is fulfilling its responsibility for reporting side effects.

This also applies to sponsored content/Promotional materials published in social media on order from the Member Company.

Subsection 5.5.2. Information intended for the public
Information published in social media is, in principle, available to the public, and information placed in social media by the Member Company itself or on behalf of the Member Company will therefore be considered targeted at the public. The Member Company is therefore obliged to comply with all requirements that apply to information intended for the public.

If some social media platforms allow the option to set up closed groups/pages with access control, and if such pages are reserved for Healthcare Personnel, it is permitted to advertise prescription-only Medicinal Products on these pages. As it must not be possible to share this

Advertising with the public, Member Companies that choose to establish a closed page with content intended exclusively for Healthcare Personnel, must operate a defined, quality-assured process for granting access to pages of this kind.

Targeted Advertisement for prescription-only Medicinal Products is permitted and can be communised 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 must be marked "for healthcare professionals."

Subsection 5.5.3. Control and responsibility for the contents
All pages in social media that have been established by a Member Company or by a third party in consultation with a Member Company must provide clear, unambiguous information that the Member Company is responsible for the page. It is also recommended that the Member Company make clear the purpose of the page, and the terms and conditions for use that apply to it. The Member Company has a responsibility to ensure that posts and all related content are in compliance with the applicable regulations, as regards the target group(s) and the purpose of the page. From a practical perspective, this means that the Member Company may in certain circumstances be required to delete comments or posts from users – if the content can be considered to constitute illegal Advertising, for example.

The Member Company must monitor comments and other communication on the Member Company's page or posts.

Subsection 5.5.4. Personal use of social media
It is often simple to use personal profiles in social media to identify which Member Company employs the user in question, so it does not take much for comments, shares or "likes" of content on a page to be considered representative of the Member Company's position. For example, if an employee likes a comment that puts forward a message about a product, this can, on closer reflection, be considered Advertising. The same applies if a Norwegian employee shares posts from the page of an overseas parent company presenting information about a new product that has been granted marketing permission in the United States, for example, but which has not yet been approved in Norway. In cases where such activity/sharing is considered Advertising, the Rules must be followed. This entails abiding by requirements for mandatory information, for example, and if the Medicinal Product is prescription-only, the requirement to limit access to Healthcare Personnel exclusively. 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.

It is recommended that the Member Companies 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 – as long as their input does not constitute Advertising for Medicinal Products.

CHAPTER 6. PROHIBITION ON CONCEALED ADVERTISING

6.1 No concealed purpose
Advertising material must not be designed to conceal its true purpose.

Enquiries regarding interaction must not be made in a covert manner.

Advertising must not be disguised as market surveys.

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.

Health and diseasedisease information must not be phrased or presented in a manner portraying it as covered advertisement.

6.2 Marking of Advertising, including content marketing
It must be clear at all times who is behind the Advertising.

Advertising that is communicated together with edited material must be clearly marked as "PROMOTIONAL MATERIAL", or the equivalent.

The same applies to other types of information about a Medicinal Product, therapeutic area or disease, if a Member Company is behind, pays for or in any way arranges for or contributes to its publication/distribution. Such information should not be designed in such a way so that it could be interpreted as being independently edited material.

CHAPTER 6 PROHIBITION ON CONCEALED ADVERTISING

Subsection 6.2 Marking of Advertising, including content marketing
All paid for product reviews, including content marketing, are regarded as Advertising and must follow the rules which apply to Advertising.

Subsection 6.2 applies to, for example, advertising supplements or other types of media where (apparently edited) information in favour of individual products, treatment options or a Member Company are conditional upon the Member Company's announcement.

The supplement/information must therefore be clearly marked to appear as Advertising and not as independently edited material. The rules for Advertising (including Chapters 7 and 8 respectively) are to be applied.

If a Member Company has written, commissioned, organised and/or financed a scientific article for publication, the relationship of the author(s) to the Member Company and how the article has been financed must be clearly shown.

PART III

ADVERTISING AIMED AT THE PUBLIC

For Advertising aimed at the public, the rules in Part III (this part) as well as those in Part II will apply.

CHAPTER 7. ADVERTISING AIMED AT THE PUBLIC

7.1 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.

7.2 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 non-

prescription packaging, and only when they are recommended for diseases or symptoms that do not ordinarily require examination or treatment by a doctor, dentist, veterinary surgeon or aqua medicine biologist. Such Promotional materials must not contain recommendations from doctors, dentists, veterinary surgeons, aqua medicine biologists or others who, by virtue of their reputation, may encourage the use of Medicinal Products.

Illustrations may convey information about the Medicinal Product's properties and use in an objective manner only, without exaggerating its effect. Illustrations must not be misleading or play on strong emotions; e.g. display bodies altered by disease or injury.

7.3 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 authorised by the government.

7.4 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 tumour diseases, chronic insomnia, diabetes or other metabolic disorders.

7.5 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.

7.6 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 ingredient (generic name) if the Medicinal Product contains only one active ingredient
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.

7.7 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 consultation with a veterinary surgeon or aqua medicine biologist, is unnecessary
b) suggest or indicate how patients or animal owners can make their own diagnoses
c) imply that recovery through use of the Medicinal Product is guaranteed or claim that there are no possible side effects
d) claim that health may deteriorate if the Medicinal Product is not used
e) be directed exclusively or primarily at children
f) refer to advice from Healthcare Professionals or experts to support the use of the Medicinal Product
g) imply that the Medicinal Product is a foodstuff, cosmetic or other common commodity
h) imply that the Medicinal Product's safety or effect is due to the fact that it is natural
i) describe medical histories that may lead to unsafe or incorrect diagnoses
j) refer to claims about recovery in an improper or misleading manner.

7.8 Prohibition on comparative Advertising

It is not permitted to claim that the Medicinal Product is equal to or better than another treatment or Medicinal Product. It is not

permitted to apply any form of comparison to non-prescription Medicinal Products.

7.9 TV Advertising

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

CHAPTER 7 ADVERTISING AIMED AT THE PUBLIC

Subsection 7.1 General requirements

When health and disease information, after chapter 10, is combined with product referencing, the advertising rules for all information applies.

Subsection 7.6 Mandatory information for Advertising aimed at the public

No reference is required for mandatory information

7.6 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.

Subsection 7.9 TV Advertising

TV Advertising is only permitted for non-prescription Medicinal Products. However, it is permitted to purchase advertising time for information that is not for advertising of Medicinal Product – e.g. information about health and diseases (see Chapter 10) or general company profiling.

Design of TV Advertising for non-prescription Medicinal Products

TV Advertising must satisfy the general requirements for Advertising aimed at the public, see Chapter 7 ("Advertising to 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, cf. Subsection 7.7 in particular, 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, normalise 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 well-contrasted against the back-ground. 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 visualisation 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 visualisation 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 visualisation 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, which patient groups should not take the Medicinal Product.

Separate sponsorship rules

"Sponsorship" refers to short "billboard" advertisements which are broadcast together with TV programmes.

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

PART IV

ADVERTISING AIMED AT HEALTHCARE PROFESSIONALS

For Advertising aimed at Healthcare Professionals, the rules in Part IV (this part) as well as those in Part II will apply.

CHAPTER 8. ADVERTISING AIMED AT HEALTHCARE PROFESSIONALS

8.1 General requirements

Prescription Medicinal Products may only be marketed to Healthcare Professionals.

Promotional materials for Medicinal Products should be plain and factual. 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 medicinal value.

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

Promotional materials should be dated and correspond with the SmPC.

8.2 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 shall then only contain the name of the medicinal product, active substance and the name of the marketer.

8.3 Reminder advertisements

The requirements in the second paragraph of subsection 8.2 need not be followed if the Advertisement is intended solely as a reminder, provided that the Advertisement contains nothing more than the preparation's name, the generic name of the active ingredient and the name of the marketer.

8.4 Accurate, balanced, honest, objective and complete

Promotional materials for Medicinal Products must be accurate, balanced, honest and objective as well as sufficiently complete to allow the recipient to form their own opinion on the therapeutic value of the Medicinal Product concerned.

Advertising should be based on the most recent evaluation of scientific material possible and clearly reflect this material. It must not distort, unjustly emphasise 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 creating dependency.

8.5 Safe

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

8.6 News

The words "news", "new" or words to that effect must not be used more than one year after a new product or new indication has been introduced onto the Norwegian market.

8.7 Correct medicinal use

Promotional materials for Medicinal Products must promote correct medicinal use by presenting Medicinal Products in a balanced way and without exaggeration of their properties or value. Promotional materials must not imply that a Medicinal Product has special properties or value unless this can be proved.

8.8 Requirements relating to documentation

All information included in Promotional materials should 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 8.9). References are not required for mandatory information (cf. subsection 8.2, second paragraph) or technical facts (e.g. marketing authorisation, pack sizes, strengths or formulations).

8.9 References

Valid references in Advertising are the SmPC or scientific work that is accessible to the recipient of the Advertising such as e.g. scientific journals, reference books and published minutes of conferences.

Periodicals that are not peer-reviewed will not be accepted as scientific sources, nor will internal company research reports.

Where Advertising refers to trials, investigations, articles etc. that have been made public, these must be correctly reproduced and clear reference must be given as to where they can be accessed.

8.10 Quotations

Quotations from medical and scientific articles should be correctly reproduced and reflect the findings and conclusions described. References should always be given where quotations are used.

Information from scientific articles should be accurately reproduced and not taken further than proposed by the original author.

8.11 Illustrations

Where illustrations are used, the source should be provided. If the illustrations have been modified, this should be made apparent.
Illustrations must not give a misleading representation of a Medicinal Product's properties or value.

8.12 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.

8.13 The Pharmaceutical Product Compendium (Felleskatalogen)

Felleskatalogen AS provides Abbreviated Product Information on Pharmaceutical Products marketed in Norway (the Felleskatalogen) online. All marketed pharmaceutical preparations from Member Companies should be entered into the Felleskatalogen and added to www.felleskatalogen.no. The text within the Felleskatalogen must correspond with the most recently approved SmPC at all times. Felleskatalog-texts are, by definition, classed as Advertising.

8.14 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 (Chapter 8) in their entirety.

CHAPTER 8 ADVERTISING AIMED AT HEALTHCARE PROFESSIONALS

Subsection 8.1 General requirements

The requirement for accuracy and impartiality means that Advertising should be objective, realistic and scientific. Statements should be verifiable and specific. Statements concerning effects should be based on quantified effect parameters and terms such as "unique" or "optimal" should not be used without valid references.

Advertising should promote sensible use by conforming to the SmPC and relevant treatment guidelines within the therapeutic area concerned.

Subsection 8.2 Mandatory information

When designing mandatory information, the following guidance is provided:

Relevant, complete and consistent with the summary of product characteristics.

"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 to 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 for the advertisement to be understood and contribute to the correct use of medicines, see section 8.4 on balanced information.

"Complies with" the SPC means that the advertisement must be in accordance

with the information in the SPC, see section 4.2. LMI considers that current industry practice, which has been to include the Fellekatalog-text in advertising, is no longer necessary. It is now sufficient that the content of the advertisement meets the requirements of Chapter 8.

To ensure balanced advertising (in line with section 8.4), parts of mandatory information, e.g. indication and contraindication, will often be integrated into the key part of the advertisement. Other mandatory information must be placed clearly visible. If one choose to write mandatory information as a separate text section in the advertisement, it must be ensured that the key message of the advertisement appears balanced. Information that is highlighted elsewhere in the advertisement does not need to be repeated in the text section.

What is to be regarded as mandatory information, and thus be included in the advertisement, must be considered specifically in each individual case. It is recommended to include the following:

- *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 relevant to the indications included in the advertisement.. If it is not obvious, include the form of administration.*
- *A brief description of the most common side effects, as well as relevant, serious side effects.*
- *Warnings / precautions and contraindications relevant to the indications.*
- *Any warnings, such as the black triangle, required to be included in advertisements by national or international authorities.*
- *Prescription group (A, B or C)*
- *If the medicine has particular prescribing rules, it should be included.*
- *An encouragement to consult the Felleskatalogen-text or SPC for more information.*
- *Marketer's name and contact information.*
- *Date of design of the advertisement.*

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 and refund must be included in advertising:

- *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 should 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.*

The font size and contrast of mandatory information must be designed in way that the text is readable by people with normal vision.

Subsection 8.3 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.

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.

For banner advertisement, please see subsection 5.2.3, second paragraph.

Subsection 8.4 Accurate, balanced, honest, objective and complete
The provision in subsection 8.4 prohibits the simplifying, excluding or selecting (i.e. cherry-picking) of information which would cause the Promotional material to mislead.

The Promotional material must always balance a positive message about the effect with relevant information that assists in preventing incorrect use of the Medicinal Product. Important safety information must be clearly conveyed in the Promotional material, and not simply as a part of the mandatory information (even if it is marked in a different colour or otherwise highlighted). Relevant safety information may have to do with contraindications, side effects or precautions. It may take the form of listing the patients who are not to use the product, or a "box" showing contraindications written in text of the same size as was used for the messages about effects. The point is that safety information must be given sufficient space and highlighting that the information is considered a natural part of the message of the Promotional material.

If the Promotional material discusses the Medicinal Product's area of application, the relevant section of the indications text should be included in the Promotional material itself.

If the Promotional material discusses reimbursement for one or more indications, the Promotional material should contain information on reimbursement-entitled use, reimbursement codes and conditions for the same indications mentioned in the Promotional material.

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.

Patient cases may be used to describe the disease of the relevant patient group. Any mention of Medicinal Products must be in compliance with the Approved SmPC, cf. Subsection 4.2, and with the Rules in general. Patient cases are not to be used to put forward claims about the properties or medicinal value of Medicinal Products. Claims regarding the properties and

medicinal value of Medicinal Products must be documented in accordance with the Rules, see Subsection 8.9.

Advertisement for antibiotics should highlight the precautionary rule in SPC 4.1, stating that use of antibiotics should be limited and that national guidelines should be adhered to.

Subsection 8.6 "New/News"
By introduced to the market, means when the product is available for sale. The one-year time limit starts from that time. The time may differ from market authorisation or decision in Beslutningsforum (approval by the Norwegian hospitals).

Subsection 8.8 Requirements relating to documentation
The requirement for documentation of information that is included in the advertising also applies to slogans and statements expressed visually.

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 8.9 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.

Conference abstracts rarely satisfy the requirement of being scientific works and may not therefore – as a rule – be used as references for claims in Promotional materials. However, should a congress abstract actually satisfy the conditions for being a scientific work accessible by the recipient of the Promotional material, it may be used as a reference. The Member Company itself must carry out a critical assessment of whether the requirement of "scientific" has been satisfied. The fact that a conference has indicated that abstracts are peer-reviewed is not in itself sufficient, since such evaluations are sometimes limited to assessing whether the subject of an abstract is suitable. The Norwegian Medicines Agency guidelines of July 2016 express negative opinions on the subject of abstracts as scientific sources.

***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 (where another researcher would, in theory, be able to conduct the research and achieve the same results), that they are as straightforward but simultaneously as systematic and as complete as possible, and that they hold the highest possible degree of validity, i.e. of truth or probability.*

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*

When presenting sales figures and market shares, IMS, 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 randomised 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 SPC is being referred to, the section number should be given – e.g. 'SPC, section 5.1' – if this is considered necessary to find the basis for the claim. Furthermore, the SPC should be dated.

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

Subsection 8.10 Quotations
Information from scientific periodicals should be accurately reproduced and not taken further than proposed by the original author.

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 well-known 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 emphasised 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 8.12 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 randomised 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 9. DISTRIBUTION OF ADVERTISING TO HEALTHCARE PROFESSIONALS

9.1 Persons to whom Advertising may be directed

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.

9.2 Address lists and registration

Address lists should be kept up to date. A Member Company should remove Healthcare Professionals from their lists when requested to do so. All treatment of personal data on Healthcare Professionals should be in accordance with the prevailing regulations on the treatment of personal information.

9.3 Use of fax, email, SMS or other forms of electronic communication

The use of fax, email, SMS or other forms of electronic communication for Advertising purposes is conditional upon the recipient having accepted or requested its use in line with current legislation.

CHAPTER 9 DISTRIBUTION OF ADVERTISING TO HEALTHCARE PROFESSIONALS

Subsection 9.2 Address lists and registration

Rules for processing personal data include, in the first instance, Act no. 38 on the processing of personal ***data (the Personal Data Act)*** *of 15 June 2018, including Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).*

PART V

INFORMATION

CHAPTER 10. HEALTH AND DISEASE AWARENESS

10.1 Purpose

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.

10.2 Information concerning treatment and treatment options

Emphasis should be placed on health and 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; in other words, levels 1 and 2.

Health and 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.

10.3 Particular diligence is called for when discussing diseases with few treatment options

Health and 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.

10.4 Specific requirements for the design of health and disease awareness

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 date-stamped 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 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-emphasise single risk factors, but rather present the risk factors in a complete risk assessment for the disease.
- Do not wrongfully emphasise particular treatment methods or a need to seek treatment.

10.5 Information should not encourage self-diagnosis

Information may be provided in order for disease to be recognised 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.

10.6 Clear disclosure of the originator

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 company-owned pages.

CHAPTER 10 HEALTH AND DISEASE AWARENESS

Subsection 10.2 Information concerning treatment and treatment options

Non-advertising

Health and disease awareness should not advertise Medicinal Products nor should it bear the hallmarks of Advertising. Images or illustrations, including branding, colours 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.

Subsection 10.4 Specific requirements for the design of health and disease awareness
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".

There are no specific requirements how references should be reproduced by this chapter. Chapters 8.8 and 8.9 do not apply.

CHAPTER 11. 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:

a) the press release concerns a news item having significant general newsworthiness
b) the mention of product names or specific active ingredients is kept to a minimum
c) only factual and brief information about the Medicinal Product is given
d) the target group of the press release is the media
e) 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 treated prior to publication

CHAPTER 11 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.

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 news-

worthiness 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).

CHAPTER 12. 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 12 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.

PART VI
INTERACTION

CHAPTER 13. PROHIBITION ON GIFTS

It is forbidden to give, offer or promise gifts, personal favours, 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 13 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 14.

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 centre names from being printed on meeting equipment.

Memory sticks
It is permitted to distribute simple memory sticks with permitted professional content. This is on condition that the memory stick does not have a disproportionately large capacity, which does not reflect a reasonable balance between the information material's needs and available alternatives (with less capacity). USB flash drives may be labelled with a company name and logo (not product).

CHAPTER 14. INFORMATION AND EDUCATIONAL MATERIAL, AND MEDICAL UTILITIES FOR HEALTHCARE PROFESSIONALS

14.1 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.

14.2 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.

Medical utilities may not be distributed directly to the public.

14.3 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 on condition that the material or medical utilities are approved according to the company's internal approval process cf. Subsection 29.3.

14.4 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".

14.5 No conditions

Materials and utilities referred to in this Chapter 14 may not be offered or distributed on condition of a consideration of any kind from the healthcare professionals, such as holding a meeting.

14.6 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.

14.7 Definition of 'low value' and how it relates to the gift provisions

'Low value' in chapter 14 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 13 is no hindrance to the distribution regulations in Chapter 14.

14.8 Undue influence prohibition

Materials and utilities referred to in this Chapter 14 may not be offered or distributed to influence unduly a decision to recommend, prescribe, buy, give, sell or administer a Medicinal Product.

CHAPTER 14 INFORMATION AND EDUCATIONAL MATERIAL AND UTILITIES FOR HEALTHCARE PROFESSIONALS

Subsection 14.1 Information and educational material

In this context, "information and educational material" is taken to mean, for example, apps, textbooks, patient brochures and so on.

Healthcare professionals may not be offered a subscription to academic journals.

Subsection 14.2 Medical utilities

Medical utility items are defined as medical equipment, demonstration sets, anatomical models and charts, inhalers, etc. The condition for distribution of utilities is that they form a necessary part of the training of healthcare professionals within a therapeutic area or for use/ administration of a certain Medicinal Product.

Medical utilities will not be distributed if they are part of the recipient's normal professional activity, such as consumable items necessary for the operation of the healthcare professional's activity, operational materials such as office requisites, creams or medical equipment such as stethoscopes and thermometers etc. These are products commercially available elsewhere and which are not necessary for training related to the use/administration of the product.

Subsection 14.7 Definition of 'low value' *and* how it relates to the gift provisions
By "low value" is currently meant NOK 400 or less. This is set by the board of LMI. Value is calculated at market price, that is, the current cost of buying the item (incl. VAT.).

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 13 should also be noted, and particular attention is drawn 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.

Subsection 14.8 Undue influence prohibition
The prohibition of undue influence is meant to protect healthcare professionals (and others) from being influenced to act in the course of their duties in a way they would otherwise not have done and which may result in undue differential treatment of patients or treatment which is not based solely on medical and professional considerations.

Influence is not necessarily negative in itself or a risk to the healthcare professional's trustworthiness. Influence may be the result of knowledge transfer. The prohibition is only meant to prevent undue influence. "Undue influence" is defined as influence that seeks to influence healthcare professionals in a manner that is based on other considerations beyond the professional and socio-economic. By other considerations is meant commercial interests or for their own advantage.

CHAPTER 15. EVENTS ORGANISED BY MEMBER COMPANIES

15.1 Scope
This chapter, Chapter 15, applies to events organized by one or several member companies.

This chapter applies to all such events regardless of what they are called and include advertising meetings, symposiums, webinars, professional trips and meetings related to planning and execution of clinical tests and non-intervention studies.

15.2 Content requirements
The main purpose of any event encompassed by this chapter (Chapter 15) should be the updating of professional knowledge.

15.3 Groups
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.

15.4 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.

15.5 Requirements relating to invitations for Advertising Meetings
Invitations for Advertising Meetings to Healthcare professionals, should include the following information:

- Time and venue of meeting
- Professional programme and its duration
- Specification of any expenses to be covered and meal provisions
- The date the invitation was prepared
- Mandatory information (cf. subsection 8.2) for all 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 26)

If meeting invitations are sent to employees of health authorities, the requirements in Chapter 17 must also be followed. This means, amongst other things, that the invitation should make it apparent that the employee must obtain permission from their employer to participate in the meeting and that the health authority 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 29.2).

The requirement for invitation under this provision does not apply to promotional visits. Promotional visits are defined as brief meetings, often lunch meetings, with a sales representative or similar/other company representative at the healthcare professional's place of work during working hours.

15.6 Choice of venue

For regulations concerning the choice of venue for meetings under the auspices of a Member Company, see Subsection 18.1.

15.7 Meetings with professional groups other than Healthcare Professionals

Advertising for prescription-only Medicinal Products may not be distributed to this group.

15.8 Prohibition on undue influence

Member Companies shall not improperly influence a decision to recommend, prescribe, buy, give, sell or administer a Medicinal Product.

CHAPTER 15 EVENTS ORGANISED BY MEMBER COMPANIES

Subsection 15.1 Scope

The rules apply to all types of events. Webinars and other types of direct procurement of events via digital media organised by a Member Company must comply with all rules in chapters 15 and 18, 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 virtual participation. In such cases, standard rules for events will apply, including subsection 15.5, chapter 18 and subsection 29.4.

Note that if recordings of presentations or meetings are posted on digital channels and are accessible at all times ('on demand'), such activities are not covered by chapter 15.

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 professionally relevant to the participants.

Advisory Boards are regulated under chapter 22.

Subsection 15.4 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 15.5 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.

Subsection 15.7 Meetings with professional groups other than Healthcare Professionals
Meetings for groups of healthcare professionals that are not covered by the definition of Healthcare Professionals in the Medicinal Products Regulations, can be organised on condition that the meeting be relevant and not feature Advertising for prescription-only Medicinal Products.

These professional groups may receive professional training in, for example, spirometry, or general training on health and disease issues.

It may be necessary to distinguish training for this group from the training of healthcare professionals, as the latter tend to be given information on prescription medicines. The rules for board are the same, however, since the regulations stipulate that meals are taken together. Here as elsewhere, board must be necessary in the completion of the professional training.

Subsection 15.8 Prohibition on undue influence
Refer to the guidance for subsection 14.7

CHAPTER 16. EVENTS ORGANISED BY THIRD PARTIES

16.1 Scope
This chapter, Chapter 16, 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.

16.2 Permitted third-party events
A Member Company may be involved in financing events encompassed by the present Chapter 16 if they are arranged by a legal entity (i.e. the organiser must have an organisation number) on the condition that the professional content of the event be controlled by an independent professional committee or the equivalent thereof.

In addition, the following criteria should be met:

(i) The event's main purpose should be to update professional knowledge.
(ii) The event may not count towards approved hours for a doctor's continuing professional development
(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) 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.
(vi) The event fulfils the requirements pertaining to events and hospitality in these Rules; refer in particular to Subsection 15.4 (Professional relevance) and Chapter 18 (Requirements for professional programme, venue, meals, coverage of expenses).
(vii) Agreements concerning the purchase of advertising or a stand at events under the auspices of a third party must be concluded in writing.
(viii) The Member Company must not contribute practical or administrative assistance with the execution of the event.

Special rules apply for events organised by health authorities – see Chapter 17.

Special criteria apply to the financing of events organised in Norway by Norwegian

Healthcare Professional Associations – see subsection 16.3.

16.3 Meetings organised by Healthcare Professional Associations Concept approval
Special criteria apply to the financing of events organised in Norway by Norwegian Healthcare Professional Associations.

16.3.1 Concept approval
A Member Company may be involved with financing events organised by Norwegian

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

A Member Company must, when agreeing upon financial contract details with the Healthcare Professional Association, inform LMI about this. It is required to submit name of the event and event date. The Member Company shall not inform LMI about the content, scope or character of the contribution.

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

16.3.2 Criteria for concept approval
Criteria for concept approval:

(i) All criteria in subsection 16.2 should be met
(ii) The Healthcare Professional Association organising the event is a registered association with Norwegian organisation number
(iii) Travel, board and course expenses for participants will be covered by the participants themselves or their employers, not the organiser
(iv) The meeting will take place in Norway
(v) The budget shows that the event will earn a maximum profit of 10% on the income
(vi) If the event requires travel, the professional content of the program needs to be a minimum of five hours per day, with the exception of travel days, here the requirement is three hours.

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 16.2 (vi) and 16.3.2 (v) are not met. Refusals should be justified.

16.3.3 Publicising the event
Once a meeting has received concept approval, it will be publicised on Digitalis.

16.4 International congresses in Norway
The requirement for concept approval does not apply to international congresses and meetings held in Norway that have EFPIA approval. Norwegian regulations will also apply.

16.5 Third-party events abroad
It is not permitted to finance participation, travel or board for Healthcare Professionals attending events abroad which have been organised by a 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-organised meetings at international congresses in accordance with Chapter 15.

16.6 Prohibition on undue influence
Member Companies should not be involved in financing third-party events in order to unduly influence a decision to recommend, prescribe, purchase, supply, sell or administer a Medicinal Product.

CHAPTER 16 EVENTS ORGANISED BY THIRD PARTIES

Subsection 16.1 Scope
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. Chapter 16 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 organise satellite symposiums. The purchase of advertising space should not generate a misleading impression that the industry is a co-organiser; 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-organiser.

Professional content needs to, at all time, be adapted to the target group.

Subsection 16.2 Permitted third-party events
A fundamental condition of third-party events is that they are organised completely independently of Member Companies. This means, for example, that a Member Company may not be involved in the planning of professional content.

Subsection 16.3 Concept approval Applications
Applications for concept approval are dealt with once a week. Electronic Applications should be sent at least 60 days before the event is due to take place. Applications must include a completed concept form, a programme and invitations to exhibit.

If the application is completed incorrectly or supplementary material is missing, the applicant will receive notification of this.

The Committee's Secretariat will send an approved application to the event organiser and the approval will be announced on Digitalis.

Applications that have not been granted approval will not be announced on Digitalis: only approved ones will be announced.

16.3.1. Concept approval briefing
Please send briefing about concept approved event financing to soknader@lmi.no. As of 1/7 2020, LMI will invoice the Member Company for each event they finance. The fee is a pre-agreed upon fee set by the board.

Subsection 16.5 Third-party events abroad
The Rule in this subsection (16.5) is often referred to as "the congress ban" 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 full digital access to conferences by some other means is contrary to the prohibition on conferences. Member Companies are not permitted to pay for or otherwise facilitate healthcare professionals' access to follow a third-party event, in its entirety, via a digital channel. However, they may pay for/facilitate digital access to individual talks held at third-party events abroad.

Own professional meetings at congresses
If the congress or any 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 programme. The meeting may not be held as an extension of the congress if this would require extended accommodation at the congress venue. Terms such 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 of the Rules for meetings organised by Member Companies (cf. Chapter 15) will

apply. Meetings should, for example, meet the requirements for Norwegian conferences – i.e. at least 90 minutes of scientific programme 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.

Member Companies may not offer financial or practical assistance with, for example, facilitating travel for participants.

Investigator meetings for Norwegian trials should not be held at foreign congresses. In the case of international trials, it may be necessary to take part in investigator meetings which are held at congresses. The main rule here is that participants at these meetings should travel home at the end of the meeting.

"A Norwegian evening" hosted by a third-party
In accordance with point 16.2, Member Companies can support meetings co-hosted 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.

Subsection 16.6 Prohibition on undue influence
Refer to the guidance for subsection 14.7

CHAPTER 17. SPECIFICALLY CONCERNING CONTACT WITH HEALTHCARE PROFESSIONALS AT PUBLIC HOSPITALS (HEALTH AUTHORITIES)

17.1 Requirements relating to appointments
Meetings between company representatives and employees at public hospitals should always be agreed beforehand in line with the health authority's authorisation procedures.

17.2 Company arranged meetings
Invitations to courses, professional meetings and the like arranged by Member Companies should always go to the health authority's supplier contacts via the normal post room.

Health authority employees may participate in activities on the condition that the enterprise is approved by the health authority. Responsibility for obtaining permission lies with the individual health authority employee.

Travel and board expenses incurred in a professional connection should be covered by the individual health authority. This provision does not apply to travel over short distances where it is practical to arrange communal transport. Modest catering in connection with professional meetings may be permitted (cf. subsection 18.4).

It must be made apparent on the meeting invitation or equivalent that the employee must obtain permission from their employer to attend the meeting and, if relevant, it must be stated that the health authority will cover travel and board.

17.3 Meetings organised by health authorities
Courses and professional meetings organised by health authorities should be arranged without financial or practical contributions from Member Companies. However, Member Companies may, by invitation, lecture or contribute to lectures at internal courses organised by a health authority.

17.4 Meetings arranged jointly by a health authority and Member Company

Health authorities may arrange professional meetings, courses, congresses or similar where Member Companies are co-organisers.

In such cases, professional rather than financial factors should form the basis of collaboration. In all programmes, invitations and similar, it should be made apparent that the Member Company is a co-organiser and that the meeting has been approved by the health authority's administrative director or their delegate. The meeting will be subject to the same rules that apply to company-organised meetings, including the rules in Chapters 4, 8 and 15.

Member Companies may not be co-organisers of courses that count towards approved hours of continuing professional development.

17.5 Training for patients and relatives

Agreements regarding training for patients and relatives (e.g. preparation of patient brochures or education and training through the Learning and Mastery Centres or other enterprises) may be entered.

Only employees of health authorities and user representatives may have direct contact with patients and their relatives.

CHAPTER 17 SPECIFICALLY CONCERNING ADVERTISING TO AND CONTACT WITH HEALTHCARE PROFESSIONALS AT PUBLIC HOSPITALS (HEALTH AUTHORITIES)

This chapter contains individual and specific provisions regarding contact between Member Companies and employees at public hospitals. All of the other provisions in the Rules pertaining to Healthcare Professionals should naturally apply to Healthcare Professionals employed at public hospitals as well.

Subsection 17.1 Requirements relating to appointments
Unannounced visits should not be made.

17.3 Meetings hosted by health authorities
The prohibition regarding financial or practical collaboration is not meant to affect traditional "lunch meetings" hosted by a Member Company, for example, during a professional day hosted by the health authorities. Please do note however, that some of the health authorities, might have own rules regarding hospitality.

Point 17.4 Meetings co-hosted between the health authorities and a Member Company.
In such meetings, the Member Company and the health authorities might contribute to the shared costs, including hospitality and professionality. For meetings hosted by a Member Company, tiles in chapter 15 and 18 applies.

CHAPTER 18. REQUIREMENTS FOR PROFESSIONAL PROGRAMME, VENUE, MEALS, COVERAGE OF EXPENSES

18.1 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 organiser 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.

18.2 Hospitality

Hospitality offered by Member Companies is only allowed in connection with events as mentioned in Chapter 15 ("Events organised by Member Companies"), 16 and 17. The

rules in chapter 18 also apply to work meetings in connection with consultancy services and clinical trials.

Hospitality should be limited to travel, meals and accommodation.

For Member Companies hosted events, member companie may cover travel and/ or overnight stays, if the professional programme must be of a minimum duration of 5 hours per day excluding the day of travel, for which the requirement is at least 3 hours, unless this is not feasible due to the travel schedule.

Remember the special limitations that apply to employees of health authorities, see *Subsection* 17.2 third paragraph.

18.3 Reasonable and necessary

All forms of hospitality offered by Member Companies must be reasonable in scope and size and must be a pre-requisite of the professional programme. If dinner is permitted, cf. subsection 18.5, this cannot be served until the professional programme is finished. This does not preclude the serving of light snacks before or during the meeting.

As a general rule, hospitality must not exceed what the recipient would normally have paid if they had paid for themselves.

Hospitality must never include financing, organisation or facilitating entertainment or social activities.

18.4 Meal rates

18.4.1 Rates in Norway

Hospitality rate A:
Up to 50 per cent of the statutory hospitality rate for “lunch/reception”.

Hospitality rate B:
Up to 70 per cent of the statutory hospitality rate for “lunch/dinner”.

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

Refer to the guidelines for the actual amount in NOK.

18.4.2 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, the total amount for meals per day covered by a Member Company, shall not exceed the current Norwegian government rates for reimbursement of meal expenses for trips abroad apply.

18.4.3 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.

18.5 Terms for hospitality and requirements for content

Hospitality can only be offered in a professional context, cf. 18.2 Duration of the professional programme, 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 in order for hospitality rate A to be applicable.
- Events/work meetings must include at least 90 minutes of professional content in order 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 virtual participation in events /work meetings at which the Member Company’s representative is not physically present, cf. 15.1, hospitality rate A applies, regardless of whether the meeting includes over 90 minutes of professional content.

18.6 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.

18.7 Prohibition on undue influence

Hospitality must not be given or offered in order to unduly influence a decision to recommend, prescribe, purchase, supply, sell or administer a Medicinal Product.

CHAPTER 18 HOSPITALITY. COVERAGE OF COSTS

Subsection 18.1 choosing destination and location

Generally, the professional program must always be the main focus and there must always be logistic and professional reasons for choosing a location and destination for events, as well as possible hospitality. Generally, common sense needs to be applied. When considering, please do remember the intention of implementing the Rules initially.

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 shall 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 (f.ex 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 emphasised that the destinations are considered natural in regard to 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.

Associated with leisure or culture activities

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 prioritised.*
- *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 centre, 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.*

Facilities: are they suited for professional meetings?

- *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 centre or at a restaurant, needs to be adequately separated from common areas, to prevent that the advertisement 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.*

Extravagance: can the overall impression of a venue appear "extravagant" or "luxurious"?

- *The assessment regarding exclusivity, can be based on own marketing or information provided at the venues 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, shall not be used by a Member Company.*
- *The facilities' actual price level needs to be assessed in accordance 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 18.1 c

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

Subsection 18.2 Hospitality

Expenses related to work meetings may be covered in connection with, for example, consultancy services, cf. chapters 21 and 22. This requires a consultancy agreement to be in place, cf. chapter 21.

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.

Serving on stand
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 18.3 Reasonable and necessary
All hospitality must be reasonable. By reasonable is meant that more expensive, food or travel than is strictly necessary to achieve the professional objective of the travel and/or event should not be paid for. This applies all year round, including the period before Christmas.

The prohibition of financing, organising, adapt for or hosting entertainment or social activities
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 organising 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 activities 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 must, in all scenarios, be conducted an overall discretionary assessment of loss of reputation. The risk for that, needs to be low.

Subsection 18.4.1 Rates in Norway
The statutory hospitality rate for lunch for 2020 is NOK 500, i.e. the maximum rate A for hospitality in 2020 is NOK 250.

The statutory hospitality rate for dinner for 2020 is NOK 1358, i.e. the maximum rate B for hospitality in 2020 is NOK 950.

Subsection 18.4.3 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 18.5 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:

<u>a) Sales representative visits</u>
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 29.4, but there is no requirement for an invitation in accordance with subsection 15.5.

If there are any doubts that a meeting is considered a sales representative visit or a meeting requiring an invitation (15.5), 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 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 18.1.

c) Events with at least 90 minutes of a professional programme
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 18.1.

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 programme 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 programme is split over two days, standard hospitality rates apply for the corresponding programme duration.

e) Work meetings
Examples of work meetings include meetings with consultants on an Advisory Board, meetings with the programme committee or meetings with investigators in connection with a clinical study. In order for hospitality to be offered, a contract for the work must already be in place, cf. the guidance on subsection 18.2. 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 programme 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 programmes 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 organised 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 programme 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 programme, 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 programme, and must be in addition to the mandatory duration for the required professional programme.

Lectures or presentations that must be considered entertainment or that are social in character are not permitted.

Subsection 18.7 Prohibition on undue influence
Refer to guidelines, item 14.7

CHAPTER 19. DONATIONS

19.1 Donations
"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 Organisations. The Rules in the present Chapter 19, do not apply when a Member Company, equally to any other business, supports charitable/non-profit/socially-beneficial causes, which are not directly or indirectly connected to the company's activity as a manufacturer of pharmaceutical products, such as support for a TV charity campaign or local children's sports.

19.2 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 Organisation.

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 CompaniesCompanies.

19.3 Application and written agreement
Donations may only be given following an application from a Healthcare Organisation 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 Organisation 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 Organisation.

19.4 Grants and prizes
Donations to individual persons are not permitted (see Subsection 19.1, second paragraph).

It is however permitted for a Member Company to 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 Organisation 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 Organisation 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 Organisation comes into effect following the application and is stipulated in a written agreement.

19.5 Documentation and transparency

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

Member Companies shall publish financial transfers and other contributions that have been made (see Chapter 26).

19.6 Prohibition on undue influence

Donations may not be offered or given in order to unduly influence a decision to recommend, prescribe, purchase, supply, sell or administer a Medicinal Product.

CHAPTER 19 DONATIONS

Subsection 19.1 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 Organisations, 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- User Organisations, see Chapter 27.

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 19.1, first paragraph.

Subsection 19.2 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 Organisation.

"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 19.3 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 19.3 exist.

The possibility of applying for a Donation should never be employed in a promotional manner by a Member Company.

Subsection 19.4 Grants and prizes

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

19.5 Documentation and transparency
Please see Chapter 26

Subsection 19.6 Prohibition on undue influence
Refer to the instructions for Subsection 14.7

A donation of e.g. equipment or Medicinal Products should never commit the Healthcare Organisation to future use of Medicinal Products or in any other way tie a Healthcare Organisation to the Member Company in an improper manner.

CHAPTER 20. PURCHASE OF SERVICES

A Member Company may only purchase services by health organisations or patient or user organisation, if the purpose is to contribute to medical research, teaching or improve patient treatment.

It needs to be a genuine need to conduct the project, and it needs to be well defined and documented. A written agreement must be signed by both parties prior to starting the project.

Such services should not be offered or purchased in order to unduly influence a decision to recommend, prescribe, purchase, supply, sell or administer a Medicinal Product.

CHAPTER 20 PURCHASE OF SERVICES

The purchase of services shall be based on true market prices. This means that there must be a reasonable relationship between price and return service.

Refer to the guidance for subsection 14.7 regarding the prohibition on undue influence.

CHAPTER 21. THE USE OF CONSULTANTS

21.1 The use of 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 (see Chapter 22) and participating in market research where this involves remuneration.

Chapter 21 regulates interactions with groups mentioned in chapter 2 and interactions with patients.

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 7 and 8, even if the assignment, as such, is not considered marketing of Medicinal Products. This includes that 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 29.The Member Company will, in such scenarios, be responsible to ensure that the lecturer adheres to the advertisement rules.

21.2 The use of Healthcare Professionals as consultants

In line with the agreements enter between the LMI and the regional health authorities and professional organisations, Healthcare Professionals employed by a company are obliged to make their employer aware of the assignment, its nature and the agreed upon compensation.

Assignments carried out by Advisory Boards and similar advisory groups should be approved by employers. The responsibility for obtaining clearance lies with the employee.

21.3 Requirements regarding the assignment

Consultant services must, to the extent it is relevant in the individual case, fulfil all the following criteria:

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 before commencement of the assignment/service
e) the written agreement should describe in detail the assignment/service and qualification of the size and payment of the compensation
f) the Member Company must keep a record of the agreements entered
g) the results of the services provided/assignments carried out should only be used in accordance with the terms of the agreement entered.

21.4 Renumeration

The compensation paid should be reasonable and represent a fair market value in relation to the assignment carried out/services provided.

21.5 Transparency and affiliation

It is strongly recommended that written agreements concerning the execution of services/completion of assignments, should include a statement that the consultant declares, by way of a verbal or written statement, that they are acting as a consultant/advisor to the Member Company on the subject of the assignment/service, or on a subject related to the Member Company in question.

Similarly, it is strongly recommended that Member Companies who have part-time employees, also practising elsewhere, ensure that the employment at the Member Company is declared whenever the person concerned expresses themselves publicly on matters relating to the employment, or to the Member Company generally.

Refer in addition to Chapter 26: "Transparency regarding the transfer of values from Member Companies."

21.6 Level of cost coverage for consultants

If a consultant participates in a domestic or international event in a consulting or advisory capacity, the rules in Chapter 18 will apply.

21.7 Prohibition on undue influence

The engagement to provide services/carry out assignments, should not be used to unduly influence a decision to recommend, prescribe, purchase, supply, sell or administer a Medicinal Product.

CHAPTER 21 THE USE OF CONSULTANTS

Subsection 21.2 The use of Healthcare Professionals as consultants

The Norwegian Code of Ethics for Doctors, Section III, Subsection 5 states that: "A doctor may not promote or market medicines or medical consumer goods. Mentions in professional medical contexts in articles, lectures etc. without gains, is not regarded as marketing." It is important that any work carried out by doctors for the industry adheres to the above statement. In the course of their lectures, doctors provide health information – i.e. general and objective information on medical questions, including fact finding, and on the treatment of diseases – without it being classed as marketing. When mentioning of a Company's Medicinal Product, however, the lecture will be treated as "Advertising" in accordance with these Rules.

Subsection 21.4 Remuneration

Remuneration rates should always be based on true market value and compensation should be reasonable in relation to the work performed.

Attention is drawn to Regulation No. 941 of 29th of August 2005 (on the limitation of opportunities for Healthcare Professionals to receive gifts, commissions, services or other benefits), which states that the term "gift" also includes compensation for work performed where the compensation exceeds an amount considered to be fair in relation to the work performed. The fee would also contravene the prohibition on gifts if it exceeded a level of compensation considered to be fair in relation to the work performed.

The existence of a genuine consultant assignment and of a written agreement between the Member Company and the consultant is a precondition for the payment of fees. Remunerating for attending normal meetings is not permitted.

Additional items it is important to remember:

- *All payments should be in accordance with the prevailing tax and reporting rules*
- *LMI recommends that individual companies define clear rules, outlining who can negotiate and sign agreements on behalf of the company*
- *Compensation for travel, hospitality and overnight accommodation expenses, can be paid in addition to agreed upon fees. This should be agreed upon beforehand and requires original- or electronic copies of receipts.*

If a consultant carries out several assignments for the same company within a given period of time, the total remuneration could be significant. Such high amounts could be viewed unfavourably or, in the worst case, as improper by the general public. It is important that the total compensation received in the course of a year, insufficient to influence the professional integrity of a consultant. Attempts could be made to avoid this situation by setting an annual maximum amount for fees payable to an individual person.

Subsection 21.7 Prohibition on undue influence
Refer to the guidance for subsection 14.7

CHAPTER 22. ADVISORY BOARDS

22.1 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 organised when necessary.

Chapter 22 regulates interaction with groups mentioned in chapter 2 and interactions with patients.

22.2 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 organisations 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 to 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.

22.3 No covert marketing

Advisory Board meetings should not be arenas for (covert) marketing or the pre-launching 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.

22.4 Execution of meetings

All Advisory Board meetings should be minuted.

The normal collaborative rules for meeting venues and any serving of meals apply (cf. Chapter 18 in particular).

CHAPTER 22 ADVISORY BOARDS

Subsection 22.1 Definition and purpose

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

General discussion groups, programme 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.

Subsection 22.2 Using external experts

An Advisory Board's task shall be clearly defined and shall 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 (cf. Chapter 21). Work executed for Advisory Boards and similar advisory groups must be approved by employers (cf. subsection 21.1, third paragraph).

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.

It should not be more than 6 experts per meeting in domestic Advisory Boards. It should not be more than 15 experts per meeting in international Advisory Boards.

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

Please note that doctors who are in specialist groups for Medicinal Product tenders are not eligible to participate in Norwegian or Nordic Advisory Boards.

Subsection 22.3 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 where 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- User Representatives or other, who are not Healthcare Professionals, cannot be hosted with the purpose of informing about prescription-only or non-prescription 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 prescription-only Medicinal Products and*
2. *how much information about the prescription-only Medicinal Products is necessary to provide.*

Subsection 22.4 Completion of meetings
It needs to be made written reports following any meeting in Advisory Boards where consultant's contribution appear clearly and with a description of any work done in preparation for or to be followed up after the meeting.

CHAPTER 23. NON-INTERVENTIONAL TRIALS OF MARKET-AUTHORISED MEDICINAL PRODUCTS

A non-interventional trial is a study of a market-authorised 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 analyse 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:
   i) 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 shall 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 observed, including any permits required by the Norwegian Data Inspectorate

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 analysed within a reasonable time frame. The medical manager is responsible for ensuring that the data is properly archived. The Member Company shall send a summarised final test report to all the participating therapists and the regional ethics committee. It shall also be made available to the Committee for Information on Medicinal Products on request
i) all ongoing trials should be recorded in a publicly accessible database and the trial results should be publicised. 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 shall also ensure that personnel have the requisite training. Any involvement of sales staff must not be connected to the marketing of Medicinal Products

CHAPTER 23 NON-INTERVENTIONAL TRIALS

f) Prohibition on undue influence
Refer to the guidance for subsection 14.7

CHAPTER 24. MEDICAL SAMPLES

24.1 Who may receive medical samples?

Medical samples may only be issued to doctors, dentists, veterinary surgeons and aqua medicine biologists who are qualified to prescribe the Medicinal Product in question to allow them to familiarise 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, dentist, veterinary surgeon or aqua medicine biologist.

Free samples may not be issued for the sole purpose of using the preparation in patient treatment.

24.2 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.

24.3 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.

24.4 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; this applies either to a new Medicinal Product that has received a marketing authorisation or to a new strength or formulation of an existing Medicinal Product that is introduced for a new indication.

The extension of the marketing authorisation 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.

24.5 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 should be accompanied by a comprehensive SmPC.

24.6 Restrictionsregarding legal status for supply

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.

24.7 Prohibition on undue influence

Medical samples must not be issued in order to unduly influence a decision to recommend, prescribe, purchase, supply, sell or administer a Medicinal Product.

CHAPTER 24 MEDICAL SAMPLES

Subsection 24.3 Quantity restrictions
A year means the 12-month period from when the doctor, dentist, veterinary surgeon or aqua medicine biologist in question sends their first written requisition.

Subsection 24.4 When can medical samples be issued?
The introductory date is defined by the Member Company itself and could be the date of the marketing authorisation, the date when the product was available or, for example, the date when the new indication was given or introduced onto the market.

Subsection 24.7 Prohibition on undue influence
Refer to the guidance for subsection 14.7

CHAPTER 25. 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 25 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. See in addition the guidance for subsection 21.3.

When market surveys are carried out amongst health authority employees, the exercise should be cleared with the employer. It is the responsibility of the Healthcare Professional to ensure that such clearance exists.

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, consideration should be given to Chapter 26 "Transparency regarding the transfer of values from Member Companies to Healthcare Professionals or Healthcare Organisations".

CHAPTER 26. TRANSPARENCY REGARDING TRANSFER OF VALUES

26.1 Reference to the EFPIA Code and the area of application of the provisions

All member organisations must disclose direct and indirect transfers of value in compliance with the regulations of this chapter. In case of doubt or for further details, refer to EFPIA's Code of Practice.

The Rules apply to all transfers of value to groups affected by (subsection 2.4), with the exception of Patient- User Organisation Representatives.

Definitions in accordance with **this chapter**:

- "Private recipient" includes any physical person ref, 2.4, with the exception of Patient- User Organisation representatives.
- Value transfers refer to direct or indirect transfers of benefits with economic value.
- 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.

Value transfers that only involve prescription-free Medicinal Products are within the framework of ordinary sales of Medicinal Products, or involving veterinary Medicinal Products are not covered by the regulations of this chapter.

The disclosure obligation does not cover the value of free samples of Medicinal Products (Chapter 24), information and educational material and medical utilities (Chapter 14), meals in a professional context within the approved rates (Chapter 18), as well as the value of ordinary information or promotional material.

26.2 Annual reporting and methods of disclosure

Transfers of values must be reported for one calendar year at a time. Reports must be made within the period of 20th – 30th of June. 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 Healthcare professionals and private recipients shall be made available on Member Companies website. Information about transfer og values to Patient- User Organisations 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. Where it is decided to give the transfers of value in Norwegian, Member Companies are encouraged to also give them in English.

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

26.3 National and international reporting

Reporting must be in accordance with the national set of regulations in the country in which the recipient 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.

26.4 Individual reporting on transfer of values to health organisations and private recipients

26.4.1 Content and conditions for individual reporting

The following must be reported:

(i) Full name of recipient

(ii) For Healthcare Organisations: place of registration
(iii) For private recipient : place of main practice
(iv) Country of main practice
(v) Physical address of main practice
(vi) Value transfers related to transfers referred to in 26.4.2 or 26.4.3 respectively.

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

26.4.2 Individual reporting in respect of a Healthcare Organisation

For the transfer of values to a Healthcare Organisation, reporting shall be conducted on an individual level in the following cases

a) Donations (see Chapter 19)
b) Purchases related to events (Chapter 17), coverage of registration fees, travel and subsistence are submitted as separate items on the form (indirect support)
c) Payment for assignments (Chapter 20). Fees for lectures and coverage of expenses will be stated as two stand-alone items on the form.

26.4.3 Individual reporting on Private recipients

Value transfers to private recipients shall be made public individually, by the company, unless anything else is stated by law.

For value transfers to private recipients reporting shall be on an individual level in the following cases:

a) Support 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 21, 22) 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.

26.5 Aggregate disclosure of transfer of values to Health organisations and private recipients

Transfers of value related to research and development as defined in subsection 26.1 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 organisation, they must only be submitted once.

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

26.6 Disclosure of contributions to Patient-User Organisations

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

For reporting, disclosure and retention requirements, the rules in subsection 26. 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- User Organisation.

For project support, the following must be disclosed:

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

For assignments, the following must be disclosed:

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

The written agreements with Patient- User Organisations must include a clause stating the disclosure of services conducted my the Member Company.

The above is not applicable to confidential information.

26.7 Methodology

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

For disclosure of value transfers to Health organisations or private recipients, 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-User Organisations, the Member Company must disclose the methods that was used when publishing and identifying transfer to Patient- User Organisations.

CHAPTER 26 TRANSPARENCY OF TRANSFERS OF VALUES

Subsection 26.1 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 C and CF) must be reported. Transfers only related to group F 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.
Indirect transmission of values refers to transfers made via a third party acting on behalf of the Member Company. Transfer to a Healthcare Organisation will 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 used.

Please note: In the EFPIA disclosure template the term "healthcare professional" is used. This corresponds, in this chapter, with the term "private recipient".

Subsection 26.2 Annual reporting and approaches for disclosure

A Member Company may sign an agreement with a private recipient 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 non-disclosure 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 26.6.

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 transmissions 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.

Subsection 26.3 National and international reporting

Value transfers to private recipients, Healthcare Organisations and Patient-Users Organisations, 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 disclosure is carried out by the subsidiary company in the country where the recipient has their main practice/place of origin. If the company does not have a subsidiary, then a website is set up in accordance with the rules in the country where the healthcare professional has their main practice. In the case of there being several company organisations in the same country, the company itself decides which legal unit that is most relevant for the disclosure.

26.4 Individual reporting regarding value transfers to health organisations and private recipients

Subsection 26.4.1 Content and conditions for individual reporting

Healthcare Organisation or private recipient?
The Member Company should describe how the company categorises the transmission of values to sole proprietorships (ENK) in the methodology note, cf. Subsection 26.6. Depending on the recipient of the transmission of values, LMI recommends the following principles for disclosure:

- *Transmissions of values to sole proprietorships are to be disclosed under Private Recipients, unless it would be technically difficult to do so for individual Member Companies.*
- *Transmissions of values to companies (AS or ANS, for example) owned by one or more Private Recipients are to be disclosed under the name of the Healthcare Organisation.*

Subsection 26.4.2 Individual reporting in respect of a health organisation
Both direct and indirect transfers of value to health organisations must be disclosed. Where a value is transferred to, for example, a professional conference organiser (PCO) (who assists the health organisation with the practical organisation of supported activities), this should be disclosed as follows:

- *The values are disclosed under the name of the health organisation (the name of the PCO can be added in parentheses); or*
- *The values are disclosed under the PCO (in these cases, the name of the health organisation benefiting from the transfer should be disclosed in parentheses).*

Subsection 26.4.3 Individual reporting about Private Recipients
For Private Recipients employed in a healthcare enterprise the rules in Chapter 17 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, cf. item 26.7.

Value transfers to private recipients must be disclosed individually.

Privacy laws, which might vary depending on each country, will decide whether complete information can be disclosed. Please do note that the health personnel number and personnel number (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 private recipients (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 has a legitimate interest in the disclosure of the value transfers. Hence, the treatment of the privacy information, including the disclosure of the value transfers to private recipients 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 private recipient's potential desire to remain confidential or their basic rights are not weighed more heavily than the legitimate interest to disclose the information.

In very special circumstances, the private recipient might object against the disclosure and 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 private recipient, 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.

Private recipients must, according to the legislation, be provided 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 health professionals and industry*
- *Incorporate in invitations from the industry that all interactions required 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 recipients.

Additionally, it needs to be informed that the privacy information will remain public in 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.

<u>When informing private recipients, the following template can be used:</u>
"The company will disclose information about value transfers (fee for assignments, travel, 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 legitimate interest.

The disclosed information will contain the recipient's name, employer, as well as the year of the value transfer, the worth of the transfer that is received by the company and why. Personal identification number and health personnel 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, including patients, the health service, the industry and the Healthcare Professionals by:

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

Transitioning period

The legal basis legitimate interest will be used already when reporting from the year 2020 (published June 2021). For agreements regarding assignments to be executed before (but not after) 31.12.2020, consent might be used.

Subsection 26.5 Aggregated reporting about Health organisations and private recipients

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 26.1), while retrospective non-interventional 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 non-interventional 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 private recipients or at their expense should be reported at aggregate level. All other non-interventional studies should be reported individually.

Subsection 26.6 Disclosure of contributions to Patient- User Organisations

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 organisations.

Subsection 26.7 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 Organisations, as well as private recipients and Patient- User Organisations, or it may be made two separate notes attached to the different

reports. The note shall 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 non-prescription/prescription medicines or types of private recipients/health organisation).*
- *How contracts that run over several years are managed.*
- *Other relevant information relating to the disclosure.*
- *How non-interventional studies are reported.*
- *How indirect transfers of value to a third party other than private recipients and health organisations are reported.*

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

CHAPTER 27. CONTACT WITH PATIENT-USER ORGANISATIONS

27.1 Principles for collaboration

Collaboration with Patient- User Organisations must happen to guarantee the following is ensured:

1. Patient- User Organisations must maintain its independence. When collaborating with the pharmaceutical industry, the pharmaceutical industry must not influence the professional or political stance of the Patient- User Organisations.
2. All collaboration with Patient- User Organisations must be based upon mutual respect. Each party's perception and decisions must be of equal significance and importance.
3. A Member Company must not collaborate with a Patient- User Organisation with the motivation to unduly promote sale, use or promotion of a particular Medicinal Product.
4. The purpose of the collaboration must be publicly available. Both financial and non-financial support must clearly appear.
5. Member Companies must encourage Patient- User Organisations to seek multiple sources of income.
6. Collaborations must be in agreement with chapter 13 about gift prohibition and 14 about information and education material and aids.

27.2 Prohibited marketing

It is not permitted to advertise for prescription-only Medicinal ProductProducts to anyone but Healthcare Professionals, reference subsection 8.1. The responsibility to ensure cohesion, including material that is distributed, to Patient- User Organisations are in accordance with the advertising rules, lies solely on the Member Company and their advertisement manager, ref. subsection 29.1.

All Member Companies must have an in-house approval process for agreements with Patient- User Organisations.

27.3 Rules for collaboration with Patient-User Organisations

27.3.1 Ways of collaboration

A Member Company may collaborate with a Patient- User Organisation to support their work, including assisting with information to the general public, patients and relatives, as well as utilise their competence.

<u>There are three ways of approved collaborations:</u>
Collaboration projects as described in 27.3.2, advertisement and stand purchase as described in 27.3.3, as well as ordinary membership and subscription to magazines. Ways of collaboration are described in chapter 20, 21 and 22.

27.3.2 Collaboration project

Patient- User organisations and Member Companies may collaborate regarding Patient- User related projects. They must be organised as a separate project, with a budget and be committed to in a written agreement that describes the project, including the genuine market value of each party's efforts.

A written agreement shall be signed by both parties prior to project start-up.

It is a condition that both parties contribute to the project. The distribution of efforts should reflect that both parties are regarded as equal partners. The Patient- User Organisation can however contribute to the project by hourly work, estimated at fair market value.

In relation to the agreed-upon project, the Member Company may provide financial support to the organisation's secretariat, however without assuming administrative control of this function.

27.3.3 Advertisement and stand purchase

A Member Company may advertise in the Patient- User Organisation's magazine or website. A Member Company may also purchase a stand at a Patient- User Organisation event, in accordance with chapter 16.2.

The purchase must be market value and be conducted in such manner that neither the general public nor the members of the organisation, can draw doubts upon the Patient- User Organisation or the Member Company's integrity.

27.3.4. Exclusivity deals are prohibited

A Member Company cannot demand to be the sole collaborator in a significant project hosted by a Patient- User Organisation.

27.4 Income estimation

The collective profits from a pharmaceutical company must not exceed 15% of the Patient- User Organisation's annual budget.

For Patient- User Organisations with a limited turnover, the collective profits from the pharmaceutical industry may not exceed 40% of the annual budget. With limited budget, means Patient- User Organisations with a budget less than NOK 250.000 turnover annually.

27.5 Use of logo or other material belonging to each party

For a Member Company to publicly display a Patient- User Organisation logo, or other branding material, requires a written permission/approval from the Patient- User Organisation. When applying for permission, the purpose to which the material will be used, must be stated clearly.

Logos/materials must not be used in such manner that a delusion of dependence is created between the Member Company and the Patient- User Organisation.

CHAPTER 27. CONTACT WITH PATIENT-USER ORGANISATIONS

Chapter 27 Contact with Patient- User Organisations

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

Member Companies must not affect text or other material coming from the Patient-User Organisation in such manner that it favours own commercial interest. This will not however, prevent Member Companies from correcting actual errors. Patient-User Organisations may ask for company input or text drafts from an open and scientific perspective.

Regarding the prohibition against unduly influence, please see subsection 14.7.

PART VII
INTERNAL PROCEDURES

CHAPTER 28. EMPLOYEES OF PHARMACEUTICAL BUSINESSES

28.1 Employees
The Rules in this chapter (Chapter 28) 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.

28.2 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.

28.3 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.

28.4 Medical sales representative activities
Medical sales representatives must act in accordance with these Rules and statutory acts and regulations.

Medical sales representatives must perform their duties ethically and responsibly.

On every occasion of a medical sales representative visiting a Healthcare Professional, they must provide, or ensure the availability of, all mandatory information (cf. Subsection 8.2) pertaining to each Medicinal Product presented, including information relating to price and reimbursement status.

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.

28.5 Training of 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.

The training is twofold, consisting of a medical part and another part pertaining to the regulations (Act and Sector Course organised by LMI; Lov- og bransjekurs).

Medical sales representatives must have basic medical and pharmaceutical knowledge. These criteria can be met with:

1. a passing grade on an approved medical sales representative exam from Sweden or Denmark, or
2. an approved study programme leading to qualification as a doctor, dentist, nurse, veterinary surgeon, pharmacist/Master of Pharmacy or Prescriptionist/Bachelor of Pharmacy.

In addition, the medical sales representative must have passed the Act and Sector Course organised by LMI.

Training of consultants who are only to deal with non-prescription Medicinal Products in their work with pharmacies
There is a separate OTC Act and Sector Course for consultants who are dealing with non-prescription Medicinal Products in their work with pharmacies only. For these consultants, the requirement of medical training mentioned in Subsection 28.5, third paragraph, above does not apply.

Other employees
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.

Time limit
The time limit 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.

28.6 Requirement for e-learning course

28.6.1 LMI's E-learning course
LMI's E-learning course aims to reinforce knowledge of the advertising rules across the whole Member Company organisation.

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.

28.6.2 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.

28.6.3 Time limit
New employees should complete the course before their first unsupervised customer contact and within three months of their appointment regardless.

The course will be updated regularly and the LMI Boardmay decide that it is to be mandatory to retake the course at regular intervals.

In the event of major revisions, the LMI will inform the Member Companies that the course must be retaken. The course is to be completed within six months of such notification having been issued.

28.7 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.

28.8 Opportunity to participate in courses counting towards continuing professional development

A small number of employees in Member Companies may participate as normal paying attendees in courses which count towards a doctor's continuing professional development when the purpose is for updating professional knowledge. Participation requires preapproval from the Committee's Secretariat. Approval normally depends on the proportion of participants from a Member Company totalling no more than 10% of the number of participants on the course in question. An accepted application does not grant the right to participate. Participation is decided by the course organiser.

CHAPTER 28 EMPLOYEES OF PHARMACEUTICAL BUSINESSES

Subsection 28.2 Medical Sales Representatives

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

Subsection 28.3 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 28.5 Training of medical sales representatives

Anyone working as a medical sales representative in a Member Company should be qualified and registered with LMI.

Medical sales representatives should have basic medical and pharmacological knowledge as well as a basic knowledge of the acts and regulations that form the framework regarding the research, distribution and marketing of Medicinal Products in Norway.

Medical sales representative training is not presently available in Norway, but it is possible to complete the training in Denmark or Sweden. The actual medical sales representative training is voluntary. To be registered as a medical sales representative in Norway however, anyone who has not completed a course of education as mentioned in Subsection 28.4, third paragraph, number 2, must have passed the medical sales representative examination. Information about the Swedish study programme is published online at www.lakemedelsakademin.se/, and information about the Danish scheme is available on www.atriumcph.com/.

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.

Participation in the course itself is mandatory. 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 28.6.1 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 28.6.3 Time limit
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 28.7 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 29. ORGANISATION AND APPROVALS

29.1 Responsibility for Member Company Advertising
Every Member Company should set up a scientific service to oversee the company's Advertising.

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

A person responsible for authorising 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.

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

Advertising material that is continuously used, should be re-authorised 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 authorisation of the Promotional material.

29.3 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 29.2 before it is used.

This includes, but is not limited to:

- Information or training material that are notPromotional materials
- Health and disease awareness
- Press releases which mention Medicinal Products
- Material that will be used in collaborative work with Patient-User Organisations

29.4 Internal monitoring
Member Companies should have a system for internal monitoring which keeps a summary of all professional and non-professional meeting agendas and an itemisation 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.

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

29.6 Promotional materials should be sent to the Committee's Secretariat
Before launch, Member Companies are obliged to send copies of all Promotional materials, regardless of the format used by the business, to the Committee's Secretariat.

The Secretariat may request a payment for each submission. Refer to the guidance for current rates.

CHAPTER 29 ORGANISATION AND APPROVALS

Subsection 29.1 Responsibility for Member Company Advertisement

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. The person responsible must inform the Norwegian Medicines Agency.

Subsection 29.6 Promotional materials should be sent to the Committee's Secretariat

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 authorisations for Medicinal Products, including those who are not members of LMI.

Examples of material

Examples of documents which shall be submitted:

- *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*

(This list is not exhaustive)

Examples of documents which should not be submitted:

- *Material connected to clinical investigations*
- *Information given to doctors in response to direct enquiries*
- *Reprints of scientific publications, treatment guidelines and other reference material*
- *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)

Electronic submission

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.

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 drift@marcello.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.

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