Nordic Compliance – overview

June 2018

Contact information:

Sweden: rikard.pellas@lif.se / www.lif.se

Norway: lars@lmi.no / www.lmi.no

Finland: laura.labart@pif.fi / jaakko.laurila@pif.fi / www.pif.fi

Denmark: sekretariat@enli.dk / www.enli.dk

Iceland: frumtok@frumtok.is / www.frumtok.is

This overview will be updated continuously

For comparison only. Further restrictions and details applies. The local Code and/or advice from the relevant national association/ethics committee should always be used. Please contact the relevant national association/ethics committee for more detailed information

Please note that there may have been changes in the national legislation/codes since the date of the publication of this overview

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Comparative Advertising

Denmark	Comparative advertising is lawful when an advertisement is correct, relevant and loyal, overall. Any comparative advertising must clearly state which products are being used for comparison. It is okay to compare studies - the claims in the advertisement must be covered fully in the referenced study. Comparisons must be objective and relate to documentable information.
Sweden	Medicinal product information that includes comparisons between effects, active ingredients, costs of treatment, etc., must be presented in such a way that the comparison as a whole is fair. The object(s) included in the comparison must be selected in a fair way, must be relevant and must be presented objectively and truthfully. Must be in line with SPC.
Norway	Medicinal product advertising aimed at healthcare professionals that include 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. Only trials that have been carried out with the intention of demonstrating a difference may be used when comparing effects and/or safety of medicinal products. Comparisons of clinical effects and/or safety comparisons should be made by presenting data from directly compared randomized clinical trials.
Finland	Only head-to-head studies can be used for comparative advertisements
Iceland	Comparative advertising must clearly state which products are being used for comparison. It is only allowed to compare products that can be compared in an objective manner and are used in the same therapeutic area/indications. Information in a comparative advertisement must be according to approved SmPCs for the compared products. Comparative advertising is not allowed in advertisements directed to the public (OTC).

	Compulsory text / minimum information - Readability
Denmark	The compulsory information must be easily legible. Legibility depends among other things on the typeface and color, font size, background color, line length, line separation and subdivision of text in the paragraph. A font size of less than 6 point in black on white would thus not normally be approved.
Sweden	Should be easily legible, were legibility depends among other things on the typeface and color, font size, background colors. Praxis states atleast Font size Time Ten 7,5. (See Chapter 1 article 19).
Norway	The mandatory information must have a clear placement with easy readable font. The font size must be sufficient for the text to be readable for people with normal good vision. It must also be sufficient contrast to the background for the text to be considered readable.
Finland	The mandatory information must be readable “without trouble”. Finland recommends that font size should be sufficient for the text to be readable for people with normal good vision. It must also be sufficient contrast to the background for the text to be considered readable. For TV-ads, the text must stay on the screen long enough to be read.
Iceland	The compulsory information must be clear and easily readable and audible. All information in an advertisement must be presented or read in a way the target group can easily read, hear or comprehend the information.

	DAC – Disease Awareness Campaign
Denmark	Allowed with restrictions
Sweden	Allowed with restrictions
Norway	Allowed with restrictions
Finland	Allowed with restrictions
Iceland	Allowed with restrictions

Definition of a Healthcare Professional
(with regards to advertisements and educational activities, etc.)

Denmark	Doctors, dentists, veterinarians, pharmacists, nurses, veterinary nurses, pharmaeconnomists, midwives, bio analysts, clinical dieticians, radiographers, social and health workers and students of these professions
Sweden	Physicians, dentists, pharmacists or other personnel within Swedish healthcare or distribution of medicinal products
Norway	Healthcare Professionals means doctors, dentists, veterinary surgeons, aqua medicine biologist, authorized nurses and pharmacists, as well students in the related subjects.
Finland	Persons whose work envisages the prescription or dispensing of medicines. The professionals entitled to prescribe or dispense medicines include: physicians, dentists, veterinarians, senior pharmacists and pharmacists. Moreover, nurses, opticians and dental hygienists who have a limited right to prescribe certain medicines. Consumers refers to persons other than those entitled to prescribe or dispense medicines.
Iceland	HCPs: those who are qualified to prescribe or distribute medicinal products, i.e. physicians, dentists, pharmacists, pharmacy technicians and registered nurses, as well as veterinarians, and students of these professions. (Please note that there are more professions that are legally classified as HCPs.)

	Entertainment
Denmark	Total prohibition against organizing/sponsoring entertainment with respect to events arranged by pharmaceutical companies (both in Denmark and abroad). In regard to sponsored third party events (where the company is not the organizer or co-organizer and therefore has no influence on the program), the different types of entertainment must be differentiated: - ”primary” (prohibited) (stand-alone performance) - ”secondary” (permitted) (activities not consisting of a special event and which is limited in its extent and/or reputation, and which does not have any entertainment value of significance for the attendee.)
Sweden	Prohibition against organizing or sponsoring entertainment. Simple (local) entertainment, not paid by company is perceived as not offered by company, and then allowed.
Norway	Prohibition against entertainment and social events with respect to pharmaceutical companies’ own events and events by third parties, sponsored by the company.
Finland	Prohibition against organizing or sponsoring entertainment. Venue may not be “renowned for its entertainment offer”.
Iceland	Organizing or sponsoring entertainment is prohibited. Meetings and congresses shall not be held at locations renowned for leisure activities. Locations renowned for leisure activities in this context refer to, for example, golf- or ski-resorts, SPAs or casinos.

	Exhibitions	Pricing	Hospitality/branding
Denmark	It must be clear to participants at a professional event just when advertising is involved and when it is solely professional education. Accordingly, advertising and marketing must be kept separate from the professional content of the event. At a medical congress, no exhibitions are permitted in the training rooms. Advertising activities must be kept separate from the professional part of the congress, for example in a foyer outside the training rooms. An exhibition stand reflects the purchase of a display area. If payment exceeds the exhibition stand's market value, this will be considered a sponsorship of the event. An exhibition area is fundamentally regarded as a commercial area. Whether or not advertising is involved depends on a general assessment of the company's overall activities in the area of the stand and whether specific medicinal products can be identified there. If this is not the case, it could for example only involve information about disease, and not advertising activity. It should be noted that the material on the exhibition stand must comply with the rules on advertising in the Promotion Code	Payment for the exhibition must be reasonable compared to the organizer's costs for exhibition arrangements and the advertising value for the pharmaceutical company. ENLI's view is thus that the price should reflect the market price for an exhibition stand, which will depend among other things on the timeframe for using the stand, the level of exposure and the nature of the location. The square meter price must accordingly comprise the actual stand price including VAT and any administration fees to the organizer. As a starting point, a square meter price of DKK 2,000 for a whole-day event in a rented, external location with about 50-80 delegates is acceptable. A higher square meter price would only be acceptable if so indicated by the market price due to the possibility of exposure or the like.	It is okay to supply guests with coffee, chocolate and bon bon's - all to be consumed at the specific exhibition stand, not to take home. A cup for coffee/water, bon bon paper can be branded with company name/logo - never with product name
Sweden	OK with Rx-promotion material in exhibition stands etc. if targeted to HCPs. The Swedish rules regards exhibition stands as sponsorship - where the counter performance is exposure of products in stands etc - and therefore has to follow LER chapter 2, section 1, article 4b. This also means a budget for the meeting is necessary, that a company's sponsorship only can cover certain expenses like lectures, facilities and food etc. However, international meetings with majority of delegates from another country are exempted from the rules of budget.	With regards to LER chapter 2, section1, article 4b, that companies sponsorship only can cover certain expenses of a meeting, means there is a limit for what companies can sponsor. So depending on size of meeting (no. of days etc.) and number of sponsors means amount can differ. Also of course, always up to each company if amount for sponsorship meets there desired exposure.	No alcohol is allowed. Coffee, juices, water and chocolate/bon bon's is okay to serve at an exhibition stand, as long as this is to be consumed at the stand. No branding allowed

	Exhibitions	Pricing	Hospitality/branding
Norway	These rules applies to professional medical 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, and with the participation of health professionals. A member company may be in involved in financing events if they are arranged by a Healthcare Organization or other registered legal entity on the condition that the professional content of the event is controlled by an independent scientific committee. The event's main purpose should be to update professional knowledge and the event should be carried out in a restricted area so that only Healthcare Professionals are exposed to Member Company advertisements/stands. Special rules apply for events organized by health authorities, and events organized in Norway by Healthcare Professional Associations. 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 medicine.		It is forbidden to give, offer or to promise gifts 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.
Finland	12 § Events organized or sponsored by the pharmaceutical industry. The main focus of the events must be on pharmaceutical information and research or other medical training. The major part of the time spent by the participants in these events must consist of scientific programme or training.		It is okay to supply guests with coffee, chocolate and bon bon's - all to be consumed at the specific exhibition stand, not to take home. Branding is not allowed.
Iceland	The focus of an exhibition must be on the pharmaceutical information and research or other medical training. Exhibition shall be carried out in a restricted area with HCPs access only.	Guidelines not available.	Gifts at exhibitions are not allowed. Light refreshments at the stand are allowed. Branding is not allowed.

	Field of Application Companies	(Who should comply with the ethical rules) Employees (in Pharmaceutical Companies)
Denmark	ENLI's rules apply to affiliated companies (members of Lif, IGL or the parallel importers – as well as other affiliated companies who are not members of an industry association) for activities in Denmark or aimed at Danish HPC's. EFPIA's member companies are obligated to comply with the rules in Denmark, but only Danish affiliated companies can be sanctioned for breaches of the code.	All employees represent the pharmaceutical company, and thus the ethical codes apply to all employees when e.g. distributing materials, issuing statements etc. The title or educational background of the employee is subordinate.
Sweden	LIFs rules apply to members of LIF, IML & FGL. The Swedish company are always responsible for activities on Swedish soil or activities targeted to Swedish HCPs.	All employees
Norway	LMI's rules apply to all member companies. A member company is defined as i) any enterprises that are members of the Pharmaceutical Industry in Norway 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. For foreign companies with authorization in Norway, the authorized representative in Norway is responsible for compliance with the rules.	
Finland	If an EFPIA member, then the company has to apply with the PIF Code.	
Iceland	An agreement with the Icelandic Medical Association is in force, formally agreeing that the EFPIA HCP code with future additions + local appendixes is the foundation of industry's interactions with HCPs. For further information see http://www.frumtok.is/about-frumtok/codes-and-ethics	

Hospitality

Denmark	Actual meals can only be offered at events consisting of at least two hours of professional content. In the event of less than two hours of professional content, there will have to be an assessment of whether the hospitality provided actually amount to a meal. When it comes to hospitality, there must be differentiation between whether it actually involves meals, which can only be provided after a minimum of 2 hours professional content, or refreshments, which is on-going hospitality without actually being a meal, such as coffee/tea, cake, fruit, etc.
Sweden	At meetings arranged by or in collaboration with pharmaceutical companies, the pharmaceutical companies may offer a moderate meal in connection with the meeting. For meals in Sweden, lunch and dinner expenses shall amount at most to the value per participant laid down by LIF at that time. For meals abroad, local rules must be followed where applicable. In the absence of such rules, the Swedish rules must be applied as far as possible. It is not allowed to pay for travel or accommodation for Swedish HCPs attending meetings and congresses etc.
Norway	Provision of hospitality from member companies to health care professionals is only permitted in respect to events organized by one or several member companies with the participation of health professionals. Hospitality will be limited to travel, meals and overnight accommodation. All forms of hospitality offered to healthcare professionals must be reasonable in scope and size and must be a pre-requisite of the professional program. Hospitality must not exceed what healthcare professionals would normally have paid if they had paid for themselves. Hospitality must never include financing, organization or facilitating entertainment or social activities. If hospitality is offered a minimum requirement for the duration of a professional program applies. Meal expenses must not exceed the set spending cap. Serving alcohol apart from moderate amounts of beer or wine accompanying food is not permitted. For events outside Norway the rates of the country where the event is being hosted must be applied. For hospital HCPs travel and board expenses incurred in a professional connection should be covered by the individual health authority for hospital. However, it is permitted to cover expenses referred to in the contract cleared with the employer.

Hospitality

Finland	In events or sessions organized or sponsored by the pharmaceutical industry, the usual local norms of hospitality shall be followed. The hospitality can extend only to the registration costs related to the event, as well as to the travelling, accommodation and meal expenses. The hospitality must be reasonable, suitable to the situation as well as secondary to the purpose of the event. In events for the marketing of prescription-only medicines, the hospitality must not be extended to persons other than healthcare professionals. The hospitality must not extend any further than what the typical guest to the event would be prepared to pay for a corresponding event.
Iceland	Meetings and congresses must be held in an appropriate venue that is conducive to the main purpose of the event and may only offer hospitality when such hospitality is appropriate and otherwise complies with the provisions of any Applicable Code(s). Therefore, meetings and congresses shall not be held at locations renowned for leisure activities. Locations renowned for leisure activities in this context refer to, for example, golf- or ski-resorts, SPAs or casinos. All forms of hospitality offered to HCPs shall be “reasonable” in level and strictly limited to the main purpose of the event. “Reasonable” in this context refers to for example: a. Travel arrangements shall generally be confined to economy class (or comparable) or the most economical fare. b. Hotel accommodation shall, in general, be confined to four star Hotels c. Meals shall not be offered at restaurants with Michelin stars, or at similarly renowned locations. d. A company neither organizes nor sponsors any stand-alone leisure activities or entertainment.

	Inexpensive (educational material and medical utility)
Denmark	Inexpensive/insignificant value is determined based on a specific assessment that reflects the general sentiment of reasonableness compared to the type of material/ equipment and within the framework of any official practice. Existing official Danish practice states that the total value of educational material and medical utility supplied from a pharmaceutical company to an individual healthcare professional, must not exceed **300 DKK in a calendar year**. The company must be able, in the event of possible proceedings at ENLI, to document to ENLI the total value (of items) from the company to a specific healthcare professional.
Sweden	Inexpensive means **450 SEK or less per item**, but should be distributed with restraints.
Norway	Inexpensive means **400 NOK**. The requirements for relevance and usefulness set clear limits for the distribution of such items. Be aware of that local regulations provide strict limitations to the total extent of the items provided (contact LMI for further information).
Finland	The price must be normal and reasonable for materials of this kind. For informative and educational materials, the **maximum value is 45 euros per item.**
Iceland	Transmission of informational or educational material is permitted provided it is “inexpensive”, directly relevant to the practice of medicine or pharmacy, and directly beneficial to the care of patients. Items of medical utility aimed directly at the education of healthcare professionals and patient care can be provided if they are “inexpensive” and do not offset routine business practices of the recipient. A threshold of **max. ISK 3.000 pr. item**.

Invitations

	Content / Program	Recipients
Denmark	No requirement to state which medicinal products will be mentioned during the meeting - but if a specific medicinal product is mentioned in the invitation/program, then the compulsory text must be included.	Special rules applies to invitations to HCP's employed at hospitals in the Capitol Region and Region of Southern Denmark. Invitations must be sent to hospital management and not directly to the individual HCP. For further, please visit ENLI's website.
Sweden	The invitation and program must state which products will be mentioned during the meeting. It is not allowed in Sweden for HCPs to promote specific products.	To Head of Clinic or appointed contact person., possible with copies relevant employees (then it must be clear to the Head of Clinic which employees).
Norway	Requirements relating to invitations for advertising meeting should include time and venue of meeting, professional program and its duration, specification of any expenses to be covered and meal provisions, the date the invitation was prepared, mandatory information for all products mentioned in the invitation, information on the treatment of personal data, the source of address registers, information on who may participate in the meeting and information on the disclosure of financial contributions in connection with the meeting, where relevant.	Special rules applies to meeting invitations that are sent to employees of health authorities (public hospitals). This means, amongst other things, that the invitation must make it clear that the employee must obtain permission form their employer to participate in the meeting and that the health authority or the participant himself/herself must cover the associated travel and accommodation costs. Invitations to courses, professional meetings and the like arranged by member companies should always go to the health authority's supplier contacts via normal post room.
Finland	In general there must be a program attached. For short product presentations at a pharmacy or a doctors work place, sending a program is not mandatory.	Invitations to the public sector must be sent to the clinic, not individual HCP's.
Iceland	Invitations are only acceptable to meetings organized by recognized organizers. Invitations to a meeting / conference organized by a Pharma Company promoting only its own products are not acceptable. If a specific medical product is mentioned in the invitation/programme, the SPC must be included.	Invitations to participate in meetings abroad have to be addressed to head of unit, who decides if the invitation is to be accepted.

Medical reprints

Denmark	Supplying medical reprints to a healthcare professional is permitted on condition that (i) this is directly relevant for clinical/pharmacy practice and (ii) it directly benefits patients. Overall, reprints must also be of insignificant value. On request: Considered informational material. Unsolicited: Considered a promotional activity which must comply with the promotional rules, including handing out compulsory text (shortened SPC)
Sweden	Considered informational material, outside SPC then it can only be given on demand from HCP. If by request, it is accepted to give an article - also including off label. If no request has been made, then the article has to be in line with the SPC. There is no demand for handing out compulsory texts along with the article
Norway	Medical reprints are considered informational material and 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 relevant for the specific HCP. It must be within label and in line with SPC.
Finland	Can be handed out, even if no request has been made from the HCP's side. It is not considered advertising, but it must be in line with the SPC and must not be laudatory.
Iceland	Can be handed out, even if no request has been made from the HCP's side. It is not considered advertising, but it must be in line with the SPC and must not be laudatory.

	Meeting venues	Accommodation
Denmark	Venues for meetings, including among other things their general reputation, design and location, must not in themselves significantly influence attendees in deciding to attend a professional event. Considerable caution should therefore be observed in the choice of venue so that no justified doubts can be raised as to whether the venue meets the professional purposes. Basically, holding professional events at for example five star hotels, gourmet restaurants (taken to mean restaurants awarded one or more stars in the Michelin Guide or similar acknowledgement in comparable independent quality assessment schemes), castles and mansions, golfing, skiing and beach hotels (in season), boat trips, etc., would not comply with the Promotion Code. Here the criterion is not whether those attending the professional event do actually have access to the leisure and entertainment activities concerned or otherwise have luxurious hospitality. The critical factor is whether the planned venue is generally regarded as "known" for its entertainment facilities, is extravagant and/or luxurious. However, logistic conditions may make out an exception to the above mentioned – e.g. a five star hotel located at a transport hub and with sufficient meeting facilities to accommodate a large conference.	Same applies as for meeting venues
Sweden	Look at the meeting facilities and location. In general no prohibition against 5-star hotels. So far only one hotel in Stockholm - Grand Hotel - is to famous for accommodating celebrities, that it cannot be used for professional meetings in the pharmaceutical industry. Se CO-decisions on venues here https://www.lif.se/etik/compliance/	Companies can never pay for accommodation for HCPs delegate for meetings, only for consultants and then same logic as for venues.
Norway	All events should be held at an appropriate venue in respect of the meeting's professional purpose. No events should be located at destinations which are associated with sporting or leisure activities, or which have a reputation of 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 abode of the participants, or b) the location of the organiser or expertise makes it more sensible to hold the event outside Norway Events organized by companies to be held outside of Norway do not longer need to be approved beforehand by the Committee's Secretariat. The companies are responsible that the event abroad satisfy all the requirements stipulated in LMI's industry rules.	Please contact LMI for more information

	Meeting venues	Accommodation
Finland	Prohibition against using 5-star hotels as meeting venues - although meeting facilities, location etc. could make out exceptions to the basic prohibition. The venue will be appropriate from the point of view of the implementation of the scientific or training program when the place has been chosen based on the availability of lecturers, smooth meeting arrangements as well as good accommodation possibilities and traffic connections. The potential for leisure activities cannot be the first priority in choosing the venue. Moreover, the events must not be organized in connection with golf or tennis tournaments, motor races or high-profile sports events or games. The events organized for the healthcare professionals of a specific geographic area (for example, Central Finland) must be organized in that area. If the event participants come from various parts of Finland, the choice of the event venue must be based on criteria that are material for the implementation of the scientific or training program. The question whether the venue is renowned for its entertainment offer or luxury will be evaluated on a case-by-case basis. For example, restaurants with a Michelin star, snow and ice hotels as well as destinations designed for golfing or other purely holiday-related purposes are such venues renowned for their entertainment offer or luxury as are not the proper venues for the meetings. However, organizing the events in congress hotels at skiing resorts or spas is not excluded as a premise. Special attention must be paid to the place being appropriate for the implementation of the scientific or training program, suitable for organizing such events.	Same applies as for meeting venues
Iceland	Meetings and congresses must be held in an appropriate venue that is conducive to the main purpose of the event and may only offer hospitality when such hospitality is appropriate and otherwise complies with the provisions of any Applicable Code(s). Therefore, meetings and congresses shall not be held at locations renowned for leisure activities. Locations renowned for leisure activities in this context refer to, for example, golf- or ski-resorts, SPAs or casinos.	

	Pictures / Patient cases	In advertisements	In scientific presentations / educational events
Denmark	Promotion of a medicinal product must be sufficiently complete and objective and it must not mislead or exaggerate the properties of the medicinal product. Information in promotion material must be in accordance with the approved SPC.	Patient cases are regarded as a subjective graphical claim for a medicinal product when used in a promotional context. A graphic illustration describing an individual effect cannot be used to document its effect on clinical studies that can document how efficacy amongst the general population can be determined. Thus, an individual claim would not be in accordance with the general principles of evidence based medicine and since claims must be documented by lawful references, the documentary requirement for such a claim would not be met. A single patient case cannot express how all patients would react to/benefit from the medicinal product and therefore patient cases do not meet the requirement for objectivity and seriousness in illustrating efficacy. Patient cases are construed as claim-making direct or indirect product-individual relations based on an image or a series of images. Accordingly a photographic image of objective symptoms of a given disease is not regarded as a potential patient case unless viewed in conjunction with a medicinal product, for example by connecting text or by implicitly implying the efficacy of the medicinal product for symptoms or the disease as a whole. Using videos of patients is assessed in the same way as images of patients and is basically not regarded as serious, objective marketing.	Patient cases can be used as part of professional events provided that the patient case is not selected by the pharmaceutical company but for example chosen by a hired speaker. There is a requirement for the use of individual patient cases to be closely associated with the professional material at the event, for example to illustrate professional knowledge that has already been reviewed at the meeting. Medical presentations consisting of a general review of patient cases, such as those that attending healthcare professionals have brought with them for general discussion, do not always have the necessary degree of detail required for the professionalism of the presentation to be assessed. Such a presentation may therefore in certain circumstances have the character of a more general exchange of experience.
Sweden	Testimonials from individual patients may not be cited as documentation. Case studies shall be formulated as typical cases so that the identity of the individual patient is kept anonymous and the studies shall remain free from subjective evaluations from the patient.	Please contact Lif Sweden for more information	Probably ok to use patient cases, while considered disease awareness. If regarding a medicinal product, then it is not okay.

	Pictures / Patient cases	In advertisements	In scientific presentations / educational events
Norway	Please contact LMI for more information	Patient cases can be used when the aim is to describe the illness of a patient group. The information of the medicinal product must be in accordance with the approved SmPC, and other requirements stated in LMI's industry rules. A patient case cannot be used to propose claims of a medicinal product's properties or medicinal value. Any claim of a medicinal product's properties or medicinal value has to be documented according to LMI's industry rules.	Please contact LMI for more information
Finland	As a premise, the use of patient cases in the pharmaceutical marketing targeted at healthcare professionals is permitted. However, it is important to remember that the information on the medicine must not be misleading (for example, different from the SPC) or it must not give an incorrect idea of the therapeutic value of the medicinal product. Patient cases in which the effects and characteristics of the medicine are presented in a more positive light than would in practice be the case in a group of similar patients on average, are misleading. Likewise, it would be misleading to present a very exceptional patient case as an example. The use of patient cases must be limited to cases of typical patients, unless there is special reason to do otherwise.	Please contact PIF for more information	Generally ok to use patient cases in meetings. It is important to remember that the information on the medicine must not be misleading (for example, different from the SPC) or it must not give an incorrect idea of the therapeutic value of the medicinal product.
Iceland	Information in promotion material must be in accordance with the approved SmPC and not misleading in any way.	Information in promotion material must be in accordance with the approved SmPC. Patient cases are not allowed. Pictures are allowed in promotional material, in accordance with the approved SmPC.	Information in scientific presentations must be in accordance with the approved SPC. Generally ok to use patient cases in meetings. It is important to remember that the information on the medicine must not be misleading (for example, different from the SPC) or it must not give an incorrect idea of the therapeutic value of the medicinal product.

	Pipelines and Pre-launch In general	Scientific Meetings (When is discussing scientific studies, etc. non-marketing or marketing?)
Denmark	There are some clear indications of when the mentioning of scientific studies as a main rule is considered pre-launch/unlawful advertising: 1. The company has published its phase III studies, 2. The company have submitted its application for marketing approval to the relevant authorities, 3. The company have a "positive opinion" from the EMA/FDA, 4. The company knows the results from its phase III study and has possibly a positive interim analysis or 5. The company is doing an indication expansion-study on an already approved medicinal product. Phase I and II: As a starting point, any mentioning of scientific studies and data related to phase I and II of a clinic development program for potential future drugs, falls outside the scope of the Promotion Code. This is due to the fact that it is not a given that a specific project ends with a marketing authorization for a specific medicinal product. Such publicity is deemed as scientific, if the information is presented in a neutral and non-promotional way. Mention of the potentially upcoming drug should thus not be laudatory. Phase III: If mentioning information from phase III studies, one must particularly consider, whether it can be considered to be advertising, especially if an application for a marketing authorization or the publication of the study is imminent. Mention of results from the phase III trial, after publication in a scientific journal, or by any other of the 5 above indications can therefore be pre-launch/unlawful advertising, when the reference occurs in a specific promotional context, thus it is to be assumed that the company from that time are working on achieving a marketing approval.	Meetings with no involvement in the program from companies, e.g. international congresses, where the content of the speakers' presentations are professional and involves professional presentations of scientific data and studies to healthcare professionals. It is thus a criteria that the presentation is made in a scientific forum, and that e.g. the medicinal company's satellite symposia is approved by the scientific congress committee and that the committee have decided to have the symposia as part of the official scientific program for the congress. Moreover, it is essential that the involved external speakers themselves decide on the format, content and angle of the subject in their presentation at the congress.
Sweden	Pipelines are not accepted in commercial areas, such as the exhibition stands at conferences/international congress‘. Forbidden to advertise a medicine before it has received a marketing authorization (unless international congress and approved in another country), strict praxis. It is for example also not allowed to present detailed mechanism of actions (even without mentioning any name of product). However, during an international congress it should be OK to show a very general pipeline overview, that very briefly consists of phase, no. of products, sickness/indication, and name/substance. The overview should be very short and general, and not the main information in the exhibition stands. This should in general not be considered marketing. OK with new study data in press releases (targeted to Journalists) if relevant, factual and balanced.	As a general rule sponsorship would be recommended (companies can not influence the agenda). For company organized educational/ scientific meetings (incl. sattelite symposiums) it is very difficult to present new data without being seen as prelaunch.

	Pipelines and Pre-launch In general	Scientific Meetings (When is discussing scientific studies, etc. non-marketing or marketing?)
Norway	It is forbidden to advertise a medicine before it has received a marketing authorization and approved price has been given. Academic and scientific information exchange concerning a medicine under development can be legitimate. The determining factor is that the information exchange does not constitute marketing ("Advertising") which is forbidden. Dissemination of information can be allowed in some cases, for example, in scientific sessions at congress or if information about the medicine is needed for an advisory board or recruitment to clinical tests. Dissemination of information may also be allowed in response to specific and wholly unsolicited questions from HCP. A member company should never invite or encourage such questions. It is recommended that questions of this nature should be handled, assessed and answered by employees in the member company's medical department.	Please contact LMI for information
Finland	The matter of pre-launch and pipeline is considered case by case. It is not allowed to promote medicinal products which do not have a marketing authorization valid in Finland. However, general information on a pharmaceutical company and their portfolio as well as research activities and results is not considered advertising (in the meaning of Finnish law on medicines) and thus is allowed, if the context is neutral. In practice, this leaves two possibilities to inform in a moderate way about non-authorized products: 1) Marketing of company itself, where in product portfolio also products without marketing authorization in Finland can be mentioned. 2) Information of company's product development programs, without any brand names, but information of the results of research programs. No therapeutic claims are allowed.	Please contact PIF for information
Iceland	All information, used/given in commercial areas, such as exhibition stands at conferences/international congress' must be in compliance with approved and published Icelandic SmPC and approved price.	

References – in general

Denmark	Substantiation of information on medicinal products must, in addition to the SPC, only include scientifically substantiated research. The research must have been published in established and independent Danish or foreign publications, professional journals or the like. The research must prior to the publication have been subject to an independent assessment (peer review).
Sweden	Information as to the quality and efficacy of a medicinal product shall be capable of substantiation by means of documentation. In this context, documentation is understood to mean any written or visual presentation containing reports on scientific facts and discoveries. Documentation to which reference is made in medicinal product information shall be of a high scientific standard. It shall have been published or accepted for publication in a scientific journal or made public or accepted for public presentation at a scientific congress or symposium. Other documentation may be cited in exceptional cases, however only on the condition that it may be considered to be of great value to those to whom it is addressed. Unpublished documentation must meet the same quality requirements as published documentation in both contents and form and must be dated and signed by the investigator in charge.
Norway	Valid references in advertising are the SPC or scientific work that is accessible to the recipient of the advertising such as e.g. scientific journals, reference books. Periodicals that are not peer-reviewed will not be accepted as scientific sources, nor will internal company research reports.
Finland	The study results and the respective sources used in pharmaceutical marketing must be reliable, and they must not be used to give a wrong or misleading impression of the medicine or its medical significance. If requested, the company must present the source material used. Reference to the source material must be made so that the source can be identified without difficulty. Illustrative material must be reproduced accurately so that the subject contents are not changed.
Iceland	Advertisement published in Professional Journal, must only include references based on approved Icelandic SmPC . In presentation/meetings the substantiation of information on medicinal products must, in addition to the approved Icelandic SmPC, only include scientifically substantiated research. The research must have been published in established and independent professional journal. The research must prior to the publication have been subject to an independent assessment (peer review).

References	Abstracts & Posters	Data on file	Foreign recommendations
Denmark	These cannot be equated with scientific articles, partly because various details of the study are often missing in abstracts and posters, and partly because abstracts and posters are generally not subject to the same strict review of the scientific value of the publication as articles in scientific journals. This fundamentally applies irrespective of whether the abstract or posters have been published and peer reviewed. If abstracts are involved relating to a scientifically supported investigation that is being published in a recognized, independent scientific journal which has been subjected to peer-review prior to publication, this can however be regarded as documentation. The Danish Medicines Agency has stated that it is not sufficient for an investigation to have been subjected to peer review prior to presentation at a scientific congress or symposium and that publication of abstracts in abstract booklets published by congress organizers or publication on a medical society's website would generally not be comparable to publication in a recognized, independent Danish or foreign scientific journal.	Such data can basically not be used since it does not satisfy the requirements for documentation.	Are not acceptable as references since these are individual countries' recommendations for the use of specific medicinal products and there may be reasons why these are not usable in Denmark. For example, recommendations are not accepted from FDA (Food and Drug Administration, (USA)) or NICE (National Institute for Health and Clinical Excellence (UK)). In the same way, neither are recommendations from WHO immediately acceptable since recommendations from them may be based on general societal or political considerations, which could mean deviating from the product summary approved by the Danish Medicines Agency.
Sweden	Posters and Abstracts are accepted as references, as long as they are coherent with the SPC (which in practice is very few)	Yes, if in line with SPC, the pharmaceutical company shall always provide such reference(s) promptly on request.	Not forbidden but must be relevant, thus often individual countries recommendations.

References	Abstracts & Posters	Data on file	Foreign recommendations
Norway	Conference abstracts rarely satisfy the requirement for being scientific works, and may not therefore, as a rule, be used as references for claims in advertisements. However, should the abstract actually satisfy the conditions for being a scientific work accessible by the recipient of the advertisement, 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. It should also be noted that the Norwegian Medicines Agency's guidelines of July 2016 express negative opinions on the subject of abstracts as scientific sources.	Please contact LMI for more information.	Please contact LMI for more information
Finland	Abstracts are in general not accepted as reference. As an rare exception an abstract can be used if there is clear proof that the therapy is superior to the earlier treatments. The unpublished study results must meet the same quality criteria applied to published results. The principal investigator must have given the consent to the publication abstract may be used. It is also required that the disease is serious, the product has an indication for the disease in question, the results are significantly better than with the other treatment, and it can e.g. be presumed that the results will change the current clinical practices. The information may never contradict with the SPC.	Such information cannot be used as reference as the marketing of a medicine must be based on the most recent SPC.	Must be individually assessed, if the recommendations are in line with the available Finnish data/recommendations. The info should be relevant to Finland and in general referring to a foreign recommendation is usually not encouraged.
Iceland	Abstracts and posters are not accepted as reference in advertisement.	Cannot be used.	Allowed, especially if there are no Icelandic treatment recommendation available and the foreign recommendations are relevant for Icelandic conditions.

References	Guidelines
Denmark	Guidelines can only be used if they are in accordance with the medicinal product's SPC and meets reference requirements. Guidelines can not be used as direct documentation and reference for claims about a medical product in a pharmaceutical advertising. The pharmaceutical company may make an additional reference to a guideline, if it contains a reference to a published scientifically substantiated study, and which satisfy the conditions for legal documentation. There must also be a reference to the article, and it is a prerequisite that the guideline does not contain information, which is non-compliant with the summary of product characteristics. It is noted that if information materials on health/disease do not - either directly or indirectly - contain information about medicines, a reference directly to the guidelines can be made, provided that these do not contain any mention of the effective use of the medicinal product in dispute with the drug's SPC.
Sweden	Guidelines from well-established associations, Swedish and foreign, can be used if they are in accordance with the SmPC, but not as an original single documentation for claims.
Norway	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
Finland	A medicine cannot be marketed on the basis of medical practice guidelines until it has a valid marketing authorization. Once the marketing authorization has been issued, the medical practice guidelines used in the marketing of the medicine must be in line with the information contained in the adopted SPC. If the medical practice guidelines have been compiled at the assignment of a pharmaceutical company, the role of the company must be clearly indicated in the guidelines in question.
Iceland	Guidelines from well-established associations, Icelandic and foreign, can be used if they are in accordance with the SmPC.

References	Review articles	Meta-analyses	EPAR
Denmark	It is acceptable to refer to review articles provided that these comply with the documentation requirements. Scientific studies can only be referred to in such review articles if each of these meets the requirements for documentation/ references.	Meta-analyses, i.e. overall statistical data processing from several medical trials, can be used as documentation provided that there is full professional cover for the statements made and provided that the study has been published in a peer-reviewed scientific journal.	Information from EMA (European Medicines Agency) may be used, if they do not conflict with the approved product information resumes. EPAR (European Public Assessment Reports) are not suitable as documentation for pharmaceutical advertisements. Studies in this connection are weighted in EMA's assessment, after which the assessment outcome is demonstrated by the SPC with the weight EMA selects. The medicinal product is given an indication on an aggregate basis of all available evidence. EPAR is an underlying document, which can include more information than is included in the SPC. You cannot choose to highlight something from EPAR in a pharmaceutical advertising, which is not recognized by the indication in the SPC, since it will be considered off-label advertising. If companies would like to use EPAR laudatory in their pharmaceutical commercials, one must therefore wait until the data is recorded in the SPC of the medicinal product.
Sweden	Should be used with caution, thus are seldom suitable as scientific reference for detailed product claims	Meta-analyses, i.e. overall statistical data processing from several medical trials, can be used as documentation provided that there is full medical cover for the statements made and provided that the study has been published an a peer-reviewed scientific journal, cf. the requirements for this clause.	The use of EPAR in pharmaceutical advertising as a reference is allowed. Must be in line with SPC.

References	Review articles	Meta-analyses	EPAR
Norway	Please contact LMI for more information	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.	It is permissible to use official statements or reports published by joint-European pharmaceutical authorities as reference. Therefore, the use of EPAR in pharmaceutical advertising as a reference is allowed. However, it must be in line with SPC.
Finland	Any study results included in the material for the marketing of medicinal products must have been published in article form in a scientific journal. Moreover, the pharmaceutical marketing material can make use of papers accepted for publications in a scientific journal and research documentation appended to the marketing authorization application. The study results and the respective sources used in pharmaceutical marketing must be reliable, and they must not be used to give a wrong or misleading impression of the medicine or its medical significance.	Same as "Review articles"	The complete EPAR can be forwarded as such as "informational material", but if the company adds any information/comments that is not mentioned in the data by the authorities, the whole thing will be evaluated as marketing and must be in line with the SPC. As in DK, you cannot choose to highlight something from EPAR in a pharmaceutical advertising, which is not recognized by the indication in the SPC, since it will be considered off-label advertising.
Iceland	Any study results included in the material for the marketing of medicinal products must have been published in article form in a scientific journal. Moreover, the pharmaceutical marketing material can make use of papers accepted for publications in a scientific journal and research documentation appended to the marketing authorisation application.	Same as "Review articles"	The use of EPAR in pharmaceutical advertising as a reference is allowed. Must be in line with SmPC.

Reminder - advertisements

Denmark	Advertisements that are directed only at healthcare professionals may be limited to the name and common name of the medicinal product. If other information is included, e.g. indications or prices, the advertisement falls outside the scope of this provision, which means all compulsory information must be included. However, company name and logo that identify the sender of the advertisement can be included.
Sweden	Pure logo reminders are not allowed according to law, a product logo in advertisement always has to be accompanied with minimum information, company contact info, etc.
Norway	Allowed (to HCPs) Must contain nothing more than preparation's name, the generic name of the active ingredient and the name of the marketer.
Finland	Allowed
Iceland	Logo reminders are allowed for OTC products only.

Sponsoring of participation in congresses etc.

Denmark	The company can sponsor events and pay for HPC's travel, registration fee and hospitality at international congresses. If, as part of attending a conference, a HCP wishes to extend his/her stay at the conference venue for holiday purposes and thus asks the pharmaceutical company to change an out/inbound journey, this would be regarded as a financial benefit provided to a healthcare professional in contravention of the general prohibition in Art. 12 of the Promotion Code. If a HCP wants to have a holiday before or after participation in a professional event, and therefore don't want to travel either out-bound or home in immediate connection with the professional event, companies may not pay for travel expenses to or from the professional activity in question, if the change of travel time is grounded in personal reasons. Pharmaceutical companies must not offer economic benefits, which are not justified by the professional context. Invitations to HCPs employed by hospitals in the Capitol Region and the Region of Southern Denmark, regarding congresses must be sent to the hospital management. Further info at ENLI's website.
Sweden	Companies cannot since 1 January 2015 pay for travel or accommodation, that is for all meetings as well in Sweden as abroad. And companies cannot pay for third-parties congress fees. Companies can in relation to congress hold their own meeting and offer dinner if relevant.
Norway	It is not permitted to finance participation, travel or board for Healthcare Professionals attending events abroad which have been organized 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 by any other means. This rule 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.
Finland	Conference participation can be sponsored for scientific events. The venue must be appropriate and purposeful for the program. It may not be renowned for its entertainment offer or luxury. The hospitality can extend only to the registration costs related to the event, as well as to the travelling, accommodation and meal expenses. The hospitality must be reasonable, suitable to the situation as well as secondary to the purpose of the event. The departure and return trips must be booked according to the congress participation requirements. The pharmaceutical company must not sponsor the physician's free time at the congress destination by paying the tickets, not even if the physician pays for the extra accommodation for the days spent at the congress destination. Paying for the free-time trips (even if combined with a business trip) can be interpreted as an offer of a bribe.
Iceland	Prior to an international event (meetings, conferences and educational travel) a written agreement shall be completed, where participation is confirmed. The agreement is between the company that funds the HCP to attend the event and the HCP. Dates of travel shall take notice of the dates of the event. If the HCP, for some specific reasons, has to travel outside the dates of the event, he/she shall him/herself handle the travel arrangements, pay any additional cost and accept responsibility for travel insurance for that part of the travel.