Nordic Q&A's – February 2021

The purpose of this Nordic Q&A is to give some practical approaches to pharmaceutical companies' compliance with local legislation and industry codes when advertising towards healthcare professionals in the Nordic countries This Nordic Q&A is a supplement to the Nordic Compliance Overview, and intends to provide a basis for a comparison of Nordic practice on specific issues. The Nordic Q&A should thus not be regarded as an exhausting review of the Nordic legislation as well as the industry's ethical rules on the highlighted topics. Further restrictions and details may apply.

The Nordic Q&A will be updated continuously. 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 Nordic Q&A.

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Basic Advertising Rules

Q1: Which rules apply for advertisements published in Scandinavian scientific journals, targeting HCPs in all the Nordic countries (e.g. Scandinavian Journal of Rheumatology)? Which language can be used in the advertisements for the main advertisement as well as obligatory information? How should obligatory information texts be handled in respect to different scope of obligatory information within the countries as well as different prescription/pricing information?

A: *If the journal is aimed at Nordic HCPs, we would expect compliance with all Nordic countries' legislation. National legislation should always be complied with. There are no requirements for Nordic language - it is okay with English. If the advertisement is aimed at Nordic HCPs you would need a compilation of the obligatory text from all the countries', you aim your advertising at.*

Q2: Is a Nurse regarded as a Healthcare Professional in all Nordic countries?

A: *The definition of a Healthcare Professional may differ from country to country. Please see below the definitions in each Nordic country.*

***Denmark**: Yes, nurses are regarded as an HCP. HCP definition in 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**: The LIF Code states that the rules concerning medicinal product information (LER Chapter 1) applies to information that, in connection with marketing of medicinal products, is targeted at physicians, dentists, pharmacists or other personnel within Swedish healthcare or distribution of medicinal products. The Swedish legislation provides that marketing of prescription-only medicines may only be provided to HCPs that are allowed to prescribe and/or administer a medicinal product. Licensed nurses may have an authorization to prescribe certain very limited medicines (e.g. a midwife may prescribe birth control pills) but may also administer (e.g. inject) prescription medicines, and therefore it is considered to be OK to include also licensed nurses in promotional information about such products. Please contact LIF for more information.*

***Norway**: Yes, by Healthcare Professionals in the Pharmaceutical Regulation means doctors, dentists, veterinary surgeons, aqua medicine biologist, authorized nurses, pharmacists, optician and dental hygienist as well students in the related subjects. Please note that for advertising meetings more relevant group of personnel may now participate when prescription drugs are presented under some circumstances, for example pharmacy technician, medical secretary, clinical nutrition physiologist etc. Please contact LMI for more information.*

***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. Nurses generally are not seen as HCPs and may therefore not be subject for Rx marketing.

***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.)*

Q3: Is a "Reminder" advertisement allowed in all Nordic countries?

A: *No, a "Reminder" is not allowed in Sweden and Iceland. It is allowed in the three other Nordic countries.*

Q4: As I understand it, in Sweden the rules on advertising only apply to the marketing division of the pharmaceutical company. Is this also the case for the other Nordic countries?

A: *No, this is not the case for any of the Nordic countries, including Sweden. The advertising rules, including national legislation, applies to everyone in the pharmaceutical company. Title and educational background are not relevant in this regard. The advertising rules applies to everyone who provides information on a specific medicine.*

Q5: For how long should a company store advertising material and how should it be archived (hard copies/electronically)? And should a copy of the material be submitted to the authorities/ local ethical committees?

A: *This may differ from country to country.*

***Denmark**: The party advertising a medicinal product shall keep a copy of, or other documentation for, the advertisement, cf. Sec. 68.1 & 3 of the Medicines Act and the advertisement must be in print or a commonly accessible digital format. Documentation for the advertisement must be retained for two years, cf. Sec. 68. 2 of the Medicines Act. It also states that in addition to the actual advertisement, information is to be retained on:*

- *The target group of the advertisement, i.e. key individuals at whom the promotion has been directed*
- *The distribution system*
- *A schedule of the media, where the advertisement was published and*
- *The period of time for which the advert was in use.*

All marketing material directed ad HCPs must be submitted to ENLI (applies for companies affiliated with ENLI).

***Sweden**: There are no legal obligations on retention of material, however it is possible to file a statement for a claim for disruptive marketing practices (this would however only be in severe cases) to IGN (self-regulation) within several years from the termination of the breach (no definitive limitation period to file a complaint exist currently, but Lif is looking into this),. There are no rules as to how it should be archived. With regards to interactions with HCPs/HCOs, other retention times apply (minimum 2 years in accordance with SKR-industry Ethical agreement, however for pharma companies this is in practice actually longer due to e.g. EFPIA Disclosure Code requirements stipulating >5 years retention)*

The IGN must receive statutory copies of promotional material (including such invitations), see Article 31/131 (LER Chapter 1). There is no obligation under Swedish law to send material to an authority.

***Norway**: Member Companies should make sure that all authorizations are kept together with the final version of approved material for at least three years. The industry rules do not mention hard copy or digital copy.*

According to the industry rules, all 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 Committee keeps it for minimum two full years.

***Finland**: PIF or the Finnish authorities don't store or collect copies of the material. PIF will store the TV and radio ads sent for pre-inspection. For a member company's perspective, a claim on a material must be started within 1 year. TV and radio ad pre-inspections are valid for 3 years.*

***Iceland**: Final version of approved promotional material should be kept for 2 years. List of all promotional material should be kept for 2 years. Industry rules do not mention hard copy or digital copy. Industry rules do not require submission of promotional material to authorities.*

Pipelines and pre-launch

Q6: If an employees' sharing of a press release of phase 3 studies is regarded as advertising, could it then be assessed to be pre-launch?

A: *Yes, it may be assessed to be prelaunch.*

***Denmark**: Yes, it may be illegal pre-launch. Normally phase I and II studies are considered science outside the scope of the advertising rules. In phase III it depends on how far along the study is; the end of phase III, just before filing for Marketing Authorization or publication of results, this would be considered illegal pre-launch of medicinal product.*

***Sweden**: Generally, press releases should have a general newsworthiness, should not contain product branding, include only factual information, should target the media only for a journalistically treatment. Pre-launch issues related to press-releases may occur, but this must be evaluated in each case.*

    

***Norway**: Generally, press releases should have a general newsworthiness, should contain minimum mention of product name or generic name, include only factual information, should target the media only for a journalistically treatment. Pre-launch issues related to press-releases may occur, but this must be evaluated in each case.*

***Finland**: Yes, it could. It needs to be 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. You may give information on company's product development programs, without any brand names, but information of the results of research programs. No therapeutic claims are allowed.*

***Iceland**: It is illegal pre-launch. In Iceland you are not allowed to advertise medicines until they have a marketing authorization and an approved price.*

Q7: Where do you draw the line between scientific information (outside the scope of the promotion rules) and promotion/advertising? When does (scientific) information become pre-launch of a new medicinal product?

A: *This may differ from country to country.*

***Denmark**: Normally phase I and II are considered science outside the scope of the advertising rules. In phase III it depends on how far long the study is – the end of phase III, just before filing for Marketing Authorization or publication of results, this would be considered pre-launch of medicinal product. The molecule name should be used – the use of common name or trade name will be considered advertising.*

***Sweden**: There is no clear distinction between phase I-II, and phase III (as in Denmark/Norway), when determining whether the information is considered within the scope of the rules for promotion, however, in-general, the risk that the activity is considered as a non-allowed pre-launch activity is increased, if it occurs closer to market authorization. Contact Lif for more information.*

***Norway**: Same as in Denmark.*

***Finland**: Scientific info is something that includes nothing that could be seen as marketing. The information on a product without a marketing authorization constitutes prohibited advance marketing to healthcare professionals if, for example,*

- *the press release uses the trade name when reporting on the results of a scientific study while the outcome of the research, for example the article, only mentions the name of the active ingredient;*
- *the press release does not concentrate, in a neutral manner, on the results shown by the study but also discusses evaluations extending beyond the study or exaggerates the significance of the*

results. The comments of investigators or other experts are permitted if they are in line with the study outcomes.

- *the press release also contains company information, other than neutral data (for example, the research focus areas can be mentioned).*

***Iceland**: It is illegal pre-launch. In Iceland you are not allowed to advertise medicines until they have a marketing authorization and an approved price.*

Minimum information/Compulsory text/Mandatory text

Q8: Do all Nordic countries have the same requirements for minimum information?

A: *No, the information from the SmPC must be supplied with an extra set of information that may differ from country to country:*

***Denmark**:*

1. *The invented name and the generic name of the medicinal product. Promotion of combination medicinal products with no generic name must include clear information on the generic names of all active ingredients.*
2. *Name of the marketing authorization holder as well as name and address of the pharmaceutical company or its agent responsible for the marketing the product.*
3. *Therapeutic indication as specified in the summary of product characteristics. In promotion material exclusively directed at a limited group of healthcare professionals, the indication text may be reduced to the extent relevant to the group concerned.*
4. *Contraindications.*
5. *Adverse reactions and risks.*
6. *Dosage.*
7. *Pharmaceutical forms.*
8. *Pack sizes.*
9. *Reference to the current price on medicinpriser.dk, if it is a pharmacy-only medicinal product.*
10. *Dispensing group.*
11. *Reimbursement status.*
12. *The date on which the promotion material was generated or last revised.*

    

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Sweden: *(unless the full SmPC is being provided). The requirements below concerns promotion to HCPs, there are other requirements for OTC and non-promotional product information intended for patients prescribed the medicine:*

1. *The name of the medicinal product,*
2. *Its dosage form and, if required, its strength,*
3. *Its active ingredients, specified by generic name which must be positioned close to the name of the medicinal product where this first appears as a headline or eyecatcher,*
4. *A balanced statement of product characteristics; this description shall contain required particulars about pharmacological group or other accepted group affiliation, together with indication or area of indications,*
5. *Required warnings or restrictions as regards the use of the medicinal product,*
6. *Such details of company name and contact information referred to in article 5,*
7. *Such details referred to in article 6, and*
8. *Information about the date on which the summary of product characteristics was compiled or reviewed,*
9. *The status of the product (e.g. Rx or OTC),*
10. *The status of the product regarding the benefits system (e.g. EF or F).If TLV has decided that the medicinal product shall be part of the benefits system; the sales price for the subsidized packages (which may be stated by a reference to fass.se according to 17.11 below), as well as explicit statement of any restrictions in the benefits system.*
11. *A reference to fass.se for further information.*

Norway*: (to HCPs, other rules for OTC)*

Any advertisement for a medicinal product directed at healthcare professionals shall contain:

a. relevant information that is complete and that corresponds with the smPC approved by the Norwegian Medicines Agency,

b. statutory dispensing conditions of the medicine,

c. price, and

d. information about pre-approved reimbursement.

    

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Finland:

All information on a medicine must always contain the following:

1. *information in line with the latest adopted summary of product characteristics (SmPC); essential for the prescription of the medicine;*
2. *statutory dispensing conditions of the medicine;*
3. *reimbursement terms and average therapy costs whenever possible; and*
4. *retail prices of various packages sizes, if possible.*

Iceland:

New Medicinal act will be effective on January 1st 2021. Regulation of pharmaceutical advertising will be updated as well.

1. The name, strength and pharmaceutical form of the product.

2. The names of all active substances, prominently displayed.

3. The name of the marketing authorization holder.

4. Approved indications and contraindications regarding the use of the product.

5. Information on the animal species for which the product is intended and, if appropriate, information on the period by which utilization must be deferred in the case of advertisements for veterinary medicinal products.

6. The text [in Icelandic] "Information on adverse reactions, interactions, warnings and other important matters can be found in the Proprietary Medicinal Products Register –www.serlyfjaskra.is" shall be prominently displayed.

7. The date of the last approved summary of product characteristics.

8. Prescription permissions and legal classification of sale and supply.

9. Clear directions on how the marketing authorization holder, or his representative who will give information about the product, can be contacted.

10. If appropriate, a clear statement to the effect that marketing authorization for the product is conditional on the supply of education material with which any person prescribing the product must have acquainted himself and, if appropriate, made known to the patient, and also by a demand that the patient be provided with certain education material before use of the product commences. It shall also be stated where the education material can be obtained from the marketing authorization holder.

    

Publication of the information under points 5-9 of the first paragraph may be omitted only if there is a clear and easily legible statement in the medicinal product advertisement to the effect that information about the product, its accompanying leaflet and the valid summary of product characteristics can be found on the website of the Icelandic Medicines Agency, www.serlyfjaskra.is.

Q9: Do the Nordic countries have the same criteria for readability in the compulsory text/minimum information?

A: *No, it may differ from country to country.*

***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**: Font size Time Ten 7,5 (in printed advertisements this has been used as a practice) , but also depending on typography according to NBL standards. (See Chapter 1 article 19) and the NBL guidance that provides additional information (NBL 948/12) https://www.lif.se/etik/ign-och-nbl/detaljer/?id=1434*

***Norway**: The mandatory information must have a clear placement with easily 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". 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. 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.*

Dosage cards

Q10: When we create dosage cards for HCPs, is it required to add the Minimum Required Text on the card?

A: *This may differ from country to country.*

***Denmark**: Yes. Dosage cards are not exempted from the advertising rules in neither the EU-Directive nor Danish legislation. A dosage card provided unsolicited to HCPs will be assessed as an advertisement and will thus need the required minimum text/compulsory text.*

***Sweden**: It is not a requirement under the Swedish ethical rules to include compulsory information on dosage cards, unless the dosing card is product branded (i.e. if it contains product logotype- then it is regarded as a promotional material).*

***Norway**: No exemption for dosage cards from the Advertising rules in Norway. A dosage card will be assessed as an advertisement according to the definition of advertising and will therefore require compulsory text.*

***Finland**: It is not a requirement to include compulsory information on dosage cards, unless the dosing card is product branded (i.e. if it contains product logotype - then it is regarded as a promotional material). This means that generally the cards need to have the minimum info.*

***Iceland**: Yes. Dosage cards are not exempted from the Advertising rules.*

QR-codes

Q11: We have been informed by our colleagues in some Eastern European countries that QR-codes are added to marketing materials directed to HCPs instead of the abbreviated Product Information (aPI) text. The QR-codes direct the user to national or EMA websites holding the full PI text. Are there any discussions around similar ways of providing aPI in marketing materials directed to HCPs in the Nordic countries?

A: *This may differ from country to country.*

***Denmark**: This has been discussed with the Danish Medicines Agency some years ago. A QR-code cannot replace the minimum information. The minimum information in Denmark includes more than information from the SmPC.*

***Sweden**: A QR-code cannot replace the minimum information in promotional materials. However, we are aware that certain "Educational Materials" (i.e. reviewed by the Regulatory Authority as part of the RMP related commitments, that companies may have as a regulatory condition of the marketing authorization) may contain QR-code to SPC/PI, and/or a website containing such information.*

***Norway:** A QR-code cannot replace the minimum information in promotional materials.*

***Finland**: A QR-code cannot replace the minimum information. The info needs to be accessible in all situations and a QR-code doesn't meet this requirement.*

***Iceland**: Not yet clarified.*

    

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Educational events

External speaker presentations

Q12: Can external speakers (contracted by a pharmaceutical company to speak at the company's educational event) talk about the company's products? And are there any requirements for such content?

A: *This may differ from country to country.*

***Denmark**: Yes, they can – but they have to stay within approved SmPC. They cannot say any more than the company itself would be able to do within the scope of the Promotion Code – otherwise the companies could just hire HCPs to give the presentations that they as a company could not (off-label, indication-extension, etc.). The company will be responsible for the presentation at their own events.*

***Sweden**: Article 8/108 of the Swedish ethical rules state that "Healthcare personnel may not participate in medicinal product information and offer their opinion as a guarantor for a particular medicinal product or recommend a particular treatment". This has been taken to mean that HCPs may not be contracted as speakers to speak about particular medicinal product. The IGN has also in case IGN-009 stated that speaker programs run the risk of being in conflict of article 8/108. However, if referring to the company's products in addition to other products can be ok provided that this is done in a balanced way so that it does not spill over to a recommendation of the product in question over other products.*

Any information about products that is provided as part of company organized activity (whether co-arranged or arranged solely by the company) must be in line with the ethical rules, such as on-label etc.

Presentations by contracted speakers as part of a company organized activity (whether co-arranged or arranged solely by the company) will fall under the ethical rules as companies are responsible for the content of the activities that they arrange.

***Norway**: If a Member Company's Medicinal products are mentioned, the lecture will be treated as "Advertising" in accordance with these industry rules as the main rule. (Subsection 21.1 Guidance). That means the company should be assessed according to the industry rules. That means also that the company rep must stop unlawful content.*

You should be aware of 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. Mention in professional medical contexts in articles, lectures and the like, not made for gain, is not regarded as marketing."

Presentations and other material shown at advertising meetings, including material from external speaker, are usually handled as marketing material, and should be sent to the Committee's Secretariat. (Subsection 29.6, guidance).

***Finland**: Yes, they can – but they have to stay within approved SmPC. They cannot say any more than the company itself would be able to do. The company will be responsible for the presentations at their own events. There must be a written contract with the speaker.*

***Iceland**: Yes, they can – but they have to stay within approved SmPC. They cannot say any more than the company itself would be able to do within the scope of the Promotion Code. The company will be responsible for the presentation at their own events.*

Industry satellite symposiums

Q13: Is an industry satellite symposium during a lunch break at an international congress (organized by a medical society) considered to be scientific information and outside the scope of the ethical rules for promotion? (e.g. is the symposium is considered a stand-alone meeting (promotion) or part of the official congress program (allowed to discuss off-label/pre-launch, etc.)?

A: *This may differ from country to country.*

***Denmark**: Industry Satellite symposiums are only considered as scientific information (outside the scope of the promotion code) if the symposium is a part of the official congress program and has been evaluated by the congress committee to be scientific relevant for the congress. Otherwise it will be considered as promotion – and in this case where the symposium is placed during lunch and if the congress committee has not validated the symposium by making it part of the official congress program, we would consider the symposium as a promotional activity.*

***Sweden**: In case invitations to the symposium are targeted to Swedish HCPs by the company (including by the mother company), then LIF code applies and the company is fully responsible for the content. If no active targeting to Swedish HCPs is performed (e.g. the symposium is only advertised at the congress website/congress bags etc., no invitations are sent to Swedish HCPs) then this does not apply.*

***Norway**: Industry Satellite symposiums are usually considered as advertising. If in doubt it is advised to contact LMI.*

***Finland**: They are considered part of the event.*

***Iceland**: Industry Satellite symposiums are only considered as scientific information (outside the scope of the promotion code) if the symposium is a part of the official congress program and has been evaluated by the congress committee to be scientific relevant for the congress. Otherwise it will be considered as promotion – and in this case where the symposium is placed during lunch and if the congress committee has not validated the symposium by making it part of the official congress program, we would consider the symposium as a promotional activity.*





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Sponsorships to HCPs

Q14: Are pharmaceutical companies allowed to sponsor an HCP's participation in a congress outside of the HCP's home country?

A: *This may differ from country to country.*

***Denmark**: Yes, sponsoring of HCP's participation in a congress/meeting outside of Denmark is allowed.*

***Sweden**: Not allowed since 1 Jan 2015.*

***Norway**: No, see LMI rules, chapter 16.5.*

***Finland**: Yes, this is allowed, if there is a solid reason for it. The invitations for HCPs in public sector need to be sent to the employer, not the individual.*

***Iceland**: Yes, this is allowed.*

Hospitality

Q15: When can we offer meals to the participants we have invited for our educational event?

A: *This may differ from country to country.*

***Denmark**: Actual meals can only be offered at events consisting of at least two hours of professional content. Refreshments such as coffee/tea, cake, fruit, etc., can be provided for meetings consisting of less than two hours of professional content.*

***Sweden**: At meetings (promotional, educational, scientific etc.) arranged by or in collaboration with pharmaceutical companies, the pharmaceutical companies may offer a moderate meal in connection with the meeting. Provision of meal must be secondary to the professional content, i.e. necessary for the execution of the meeting. At remote participation (e.g. Webinars), meals may not be offered (prohibited, unless there is a representative from the company in the same room as the HCPs that attend the meeting via link).*

***Norway**: There are two different meal rates in Norway. The rate A is typically used for sales rep meetings with HCPs and are also used for shorter meetings of minimum 45 minutes. The other rate B is typically used for dinners. Rate B requires minimum 90 minutes of professional content. It is not allowed to serve dinner during or before a meeting.*

***Finland**: Majority of the program must be educational or scientific. 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.*

    

***Iceland**: Meals may be offered if the majority of the program is educational or scientific. In events or sessions organized or sponsored by the pharmaceutical industry, the local criteria of hospitality is followed. The hospitality must be reasonable, suitable to the situation as well as secondary to the purpose of the event.*

Entertainment

Q16: Is entertainment banned from all events in the Nordic countries or are some type of entertainment still allowed?

A: *This may differ from country to country.*

***Denmark**: Total prohibition against organizing/sponsoring entertainment with respect to pharmaceutical companies' own events (both in Denmark and abroad).*
With respect 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 assessed:

- *"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 (e.g. a group of HCPs attending the meeting will sing and play music together in connection to a dinner, but no hiring of musicians/performers/DJ etc.) .*

***Norway**: Prohibition against entertainment and social events with respect to pharmaceutical companies' own events and events by third party sponsored by company.*

***Finland**: Prohibition against organizing or sponsoring entertainment. Venue may not be "renowned for its entertainment offer".*

***Iceland**: Organizing or sponsoring entertainment is prohibited.*

Meeting venues

Q17: Do all Nordic countries have the same rules regarding meeting venues?

A: *Yes and no. All countries have a rule banning the use of extravagant and luxurious meeting venues. But the interpretation of what "extravagant and luxurious" means may differ from country to country. Please see below:*

***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 "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.

***Sweden**: Look at the meeting facilities and location. In general, 3-4 star hotels are used in Sweden. One hotel in Stockholm - Grand Hotel - is to famous for accommodating celebrities and has a luxury image, and it cannot be used for professional meetings in the pharmaceutical industry. See CO-decisions on venues here https://www.lif.se/etik/compliance/*

***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 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.

***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.

***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.*

Exhibition area

Q18: Who is responsible for the pharmaceutical company's exhibition area – the HQ of the pharmaceutical company (who have paid and arranged for the exhibition) or the sister company in the country, where the exhibition takes place?

A: *This may differ from country to country.*

***Denmark**: The Promotion Code only applies to the ENLI-affiliated companies – although corporate responsibility applies in accordance with EFPIA´s Code of Practice.*

ENLI's view is that a company associated with ENLI can only be regarded as having joint liability for the activities, if it is regarded as being the co-organizer of these. This means that the company concerned must be sufficiently involved in the activity concerned. ENLI's assessment is that the company must have taken clear, direct steps in developing and/or undertaking the specific activity. The company could perfectly well assist HQ with knowledge about how the Danish rules should be interpreted so as to ensure compliance with them. On the other hand, if more active steps are taken in developing or undertaking the activity, the company concerned will be moving in the direction of liability as co-organizer. This could for example be by way of the company assisting in the selection of Danish healthcare professionals for participation in a specific medical event or if the company were to have influence on the content of a professional program or proceedings in a professional event. Likewise, if the Danish subsidiary actively participates in the parent company's exhibition stand at a congress, etc.

***Sweden**: In the country where it takes place. For Sweden our ethical rules hold the local company responsible for all activities that happens in Sweden & targeted Swedes.*

***Norway**: The Code applies to the Norwegian member of LMI.*

Finland: *This depends on the situation. Usually the local company would be seen as responsible. Marketing directed to Finnish doctor abroad must also comply with the Finnish Code of Ethics.*

Iceland: *The responsibility lies with the local company. Marketing promotional material has to be in compliance with EFPIA's and Frumtök's Code.*

Q19: Can a pharmaceutical company divide the exhibition area between promotional materials/activity and scientific information (medical booth)? And if so, which rules apply for the specific areas of the exhibition area?

A: *Yes, you can have a divided booth, but the same rules apply. The exhibition area is a commercial area, and therefore the Advertising rules apply for all activities in the exhibition area, and all activities will be seen as promotional.*

Q20: How is the term "Individual correspondence" interpreted with regard to an exhibition area? (Face to face dialogue (responding to questions – is that within or outside the scope of the advertising rules?))

A: *This may differ from country to country.*

Denmark: *The exhibition area is considered to be commercial, and thus questions from HCPs to pharmaceutical companies cannot be seen as completely unsolicited.*

The specific exception in the advertising rules for individual correspondence applies to written communication, and only to individual persons. In a written reply regarding individual correspondence, one can answer specific questions relating to e.g. off-label use. However, it must be ensured that one does not articulate an answer so wide that it takes on the character of advertising, including illegal advertising claims for off-label use.

An oral answer of a question in an assembly is thus not covered by this exception, because it no longer has the characteristics of individual correspondence, nor is it in writing. Regarding oral questions in meetings, one should only mention what one's medicinal product is approved for and nothing else. Otherwise there is a risk of a commercial situation, since the definition of advertising is interpreted very broadly.

Sweden: *Push & pull principles apply; thus, you can answer direct questions regarding new studies etc. not in SmPC, but not give more than intended or take the opportunity to do so. Answers to specific enquiries, possibly including any plainly designed material of a nonmarketing nature, that is needed for answering specific, unsolicited questions about a particular Medicinal Product is not regarded as "Advertising".*

***Norway**: Answers to specific enquiries correspondence, possibly including any plainly designed material of a nonmarketing 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.*

***Finland**: Unsolicited questions on normally banned topics, such as off label may be answered shortly, if asked. For further info the questions should be directed to the scientific unit.*

***Iceland**: Exhibition areas are considered to be commercial, thus conversations and answers to HPS's questions shall comply with EFPIA's and Frumtök's standards for interactions with healthcare professionals. Off label use and unsolicited questions should be directed to medical as a medical request.*

Q21: Are pharmaceutical companies allowed to serve drinks and food in the exhibition area?

A: *This may differ from country to country.*

***Denmark**: Coffee, water and small pieces of candy (chocolate, bon bons) would be okay, as long as it is not considered luxurious and is to be consumed at the exhibition stand. It will be okay with company branding (name and logo), but never okay for product name.*

***Sweden**: 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.*

***Norway**: Serving on stand may be permitted, if the serving does not appear or function as a gift or a meal. Examples of permitted serving: pieces of fruit, assorted chocolates, cookies, small brownies, simple coffee serving etc., that are suited for consuming on the spot. Alcohol is not permitted.*

***Finland**: 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**: Gifts at exhibitions are not allowed. Light refreshments at the stand are allowed. Branding is not allowed.*

Q22: Are pipelines allowed in the exhibition area – and under which restrictions, if any?

A: *This may differ from country to country.*

***Denmark**: Yes, for studies in phase I and II. Normally phase I and II are considered science outside the scope of the advertising rules. In phase III it depends on how far long the study is – the end of phase III, just before filing for Marketing Authorization or publication of results, this would be considered pre-launch of medicinal product. The molecule name should be used – the use of common name or trade name will be considered advertising.*

***Sweden**: Pipelines are not accepted in commercial areas, such as the exhibition stands at conferences/international congress', unless the product has been approved in another country and the*

conditions for international congress have all been met (see LER Chapter 2, section 1, Article 4, and EFPIA Code Article 8). Note- this view has been challenged by the Regulatory Authority recently, and the situation is unclear at present.

In the non-commercial exhibition, 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.

***Norway**: Proactively mentioning of scientific studies and data related to a Pharmaceutical pre-launch, is usually prohibited, due to point 4.1, stating that advertisement for products without a Marketing Authorization is prohibited. Medical or scientific information exchange related to pharmaceuticals, can however not be considered advertisement, and therefore legitimate. Upon such decision, it is imperative whether the specific information is conveyed to promote the sale of the product. It needs to be individually reviewed whether, or not, the conveying of information was conducted to promote sales of a product. Originally, it will be considered proactive mentioning of a pharmaceutical development when: 1) The product development has reached the stage where a Marketing Authorization has been submitted (either nationally/EMA/FDA etc.), or 2) Introduction of product to market is imminent (less than one calendar year is considered imminent) or if a Member Company has published a phase III study or if a Member Company is familiar with the results of the phase III study and has temporary analysis' available) 3) Information about potentially new indications for an already approved pharmaceutical is provided. The context in which the information is provided, will be highly relevant when reviewing whether pipeline information is considered Advertisement.*

***Finland**: Yes. But it may not be used for pre-marketing and can easily be interpreted as such. The booth will be looked as a whole and product ads in combination with a pipeline may be problematic.*

***Iceland**: No.*

Q23: What are the rules on comparative advertising at an exhibition area??

A: *Same as in general. That means, very strict rules and usually the comparison has to be based on the SmPC's or a study. Must be done in an appropriate and clear way. Please note that in Finland, comparisons are only allowed if using head-to-head studies.*

Virtual meetings

Live streaming/on-demand

Q24: Are pharmaceutical companies allowed to sponsor an HCP's access to live streaming or on-demand presentations from an international congress?

A: *This may differ from country to country.*

***Denmark**: Yes.*

***Sweden**: No, not allowed to pay for registrations fees, however for company satellite symposium it may be OK to provide access free-of-charge, provided that the content is in accordance with LER/do not interfere with laws/regulations concerning non-allowed promotion*

***Norway**: Sponsoring of full digital access to live streaming is not allowed. First of all, such full access is in conflict with the so-called Kongressvedtaket (which forbids financing the general training of HCPs). It may also be considered as a gift, which is not allowed. Sponsoring of access to parts of a virtual congress (company meetings where parts of congress is being streamed) may be allowed if the content complies with advertising rules.*

On-demand will be a selection of sections from the congress, and this is further considered as a promotional action made by the company. In this way the on-demand presentation will have to fulfill the same requirement as e.g. a promotional meeting, and off label information will not be accepted. It will also be a matter of costs, as an on-demand access may be ex-pensive and therefore considered as a gift of great value, i.e. not allowed.

***Finland**: Yes, but with certain limitations. See answer to next question.*

***Iceland**: Yes, but in line with EFPIA's and Frumtök's standards.*

Q25: Are live streaming or on-demand sessions from a congress – but placed on a pharmaceutical company's website – considered professional education or advertising?

A: *This may differ from country to country.*

***Denmark**: In the case of live transmissions, these can be equated with a professional meeting, where one is physically present. Thus, if a company chooses to provide live access to the full congress, it will not be considered as advertising, but would be considered as purely scientific content (though please see below). However, this applies only for those presentations, which is part of the official congress program.*

If a company via its own website, or via a contracted third party wants to live stream posts from a congress, the company must familiarize themselves with the program prior to livestreaming, including assessing whether there are posts which may include mention of the company's medicines, which could constitute advertising.

For material that a company places on its website and make available on demand, it will also be the company's responsibility to ensure that there is no material, which may constitute illegal advertising for the company's medicines, including pre-launch and off-label. It will depend on a specific assessment. ENLI recommends that companies use "neutral" sites for on-demand solutions. Offering live streaming or on-demand access directly from the congressional provider will also be able to minimize the risk of confusion with advertising.

    

For further on this, please see ENLI's Guide on International Congresses on www.enli.dk/en.

***Sweden**: Not applicable, it is not allowed to provide such congress content free-of charge (see question above). Contact Lif for discussion concerning opportunities to sponsor digital congresses.*

***Norway**: Live streaming on a website may be possible in case you are sure that the presentation does not contain any information about medicinal products or any treatment guidelines. Usually, such congress presentations contain information about medicinal products and/or treatment guidelines, and it will not be possible for the company to make sure that no off-label information is being presented.*

On-demand on a website is possible, but usually you will need to edit the presentation. In this way the on-demand presentation will have to fulfill the same requirement as e.g. a promotional meeting, and off-label information will not be accepted.

***Finland**: Depends on the content.*

In order to be comparable to participating to the congress live and not creating direct responsibility for all the content, the preconditions, that need to be met:

- *The event is organized by a third party (e.g. an international congress) and there is an independent scientific committee that is responsible for the program. It must be possible for other parties to watch the contents (free or buy purchase) and not just for the participants paid by the member company.*
- *The remote participation must be comparable to attending the congress live. Therefore, the watcher must be able to freely select the content to be watched, mainly from several options.*
- *Watching the broadcasting should mainly happen in real time (live). Watching recorded content may be directly comparable to live content, if the invitation to watch the content has been sent in good time before the live event and the content of the recording has remained unchanged (no additions or removals).*
- *Streaming of the congress must always be presented in a neutral manner. The streaming platform and environment may not contain any marketing or other elements (e.g. branded colors), which together with the content could be seen as marketing or other prohibited entity.*
- *The invitation process must follow the normal rules governing it. The invitations must e.g. be sent to correct recipients.*

***Iceland**: If session does not contain any information about branded products advertising or any treatment guidelines it is allowed with restrictions and by invitation to HCPs only.*





Hospitality/Catering at virtual meetings due to COVID-19

Q26: Can pharmaceutical companies provide meals or snacks at virtual meetings with HCPs? (meetings organized by the pharmaceutical company)

A: *This may differ from country to country.*

***Denmark**: Generally, no. ENLI recommends that no catering be offered for company-organized virtual meetings during COVID-19, as this may send the wrong signal, and could cause offence, bring discredit upon or reduce confidence in the pharmaceutical industry, cf. Art. 1 of the Promotion Code. If there is a representative from the company in the same physical room as the HCPs that are following the meeting via link/virtual access, then snacks (meals if more than two hours of professional content) would be possible, as the meeting is not a pure virtual meeting but a 'hybrid'.*

***Sweden**: No – prohibition in the code. The only exception is if there is a representative from the company in the same physical room as the HCPs that are following the meeting via link/virtual access (then the meeting is not a pure virtual meeting but a 'hybrid').*

***Norway**: Strict rules apply – under revision.*

***Finland**: Not to their homes, but possible, if this is at their workplace.*

***Iceland**: Yes.*

Q27: If a pharmaceutical company sponsor an individual HCP attending a virtual congress, may the company provide meals or snacks for the HCP?

A: *No – not according to EFPIA's COVID-19 guide:*

"Regarding the hospitality provided during virtual Events, Member Companies cannot provide hospitality for the Healthcare Professionals attending individually a virtual third-party organized Event."

***Sweden**: In addition to EFPIA guidance this is prohibited in the Swedish code (see also question 26). The same prohibition on provision of meal applies for both company organized and third-party-organized meetings/events.*

Educational material and medical utility

Q28: Educational material and medical utility items given to an HCP must be "inexpensive". Is "inexpensive" interpreted the same way in all Nordic countries?

A: *No, "inexpensive" is not interpreted the same way in every Nordic Country. Please see below:*

***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. Up to date information is to be found on www.frumtok.is.*

Social Media

Q29: Can a posting on an employees LinkedIn-profile, stating "*Good news for patients – look at my company's pipeline*" be considered to be an advertisement?

A: *Yes, it can. The concept of advertisements for pharmaceutical products is interpreted very broad. One example is the so-called "Damgaard case" (C-421/07), in which the EU Court of Justice held that information about a medicinal product communicated by a third party, namely about its curative or prophylactic properties, could be regarded as advertising, even though the third party was acting on his own initiative and legally and actually was completely independent of the manufacturer or seller of such a medicine.*

Q30: Is there a difference between "liking" and "sharing" information on social media?

A: *This depends on the platform and the terms (actions). It will need to be analyzed separately every time. On LinkedIn or Facebook, liking and sharing have more or less the same effect. The only difference is the top line of the post.*

Q31: Does it matter (regarding the evaluation on whether the posting is advertising) if the employee is the CEO, Marketing Manager or the head chef in the kitchen?

A: *What matters is the employee's intention – not his/her title or educational background.*

Q32: Who is liable for an employee's illegal advertising on his private social media account?

A: *According to EFPIA's principles on the use of digital channels, the pharmaceutical company can be made responsible for employee sharing of information on employees' private profiles on social media, including:*

(a) when employees can reasonably be perceived as representing the member company, or

b) if the employees are instructed, approved or facilitated by the member company to share information on social media.

Member companies should therefore have internal guidelines on how their staff should behave on digital media, including on their own personal profile activities.

The employee may be liable according to national legislation, regardless of whether the pharmaceutical company is made liable in line with industry codes.

Self-regulation

Q33: Are advertisements for OTC's to the public covered by the ethical codes in all the Nordic countries?

A: *No. The industry code in Denmark and Iceland only applies on activities targeted HCPs. Finland, Sweden and Norway have specific rules regarding OTC advertisements targeted the public.*

Q34: If one complaint about another company to the self-regulation bodies, do you have to inform the company you are complaining about prior to sending in the formal complaint?

A: *This may differ from country to country.*

***Denmark**: There is no obligation to inform the company you're complaining about prior to sending the complaint to ENLI. However, ENLI does encourage companies to communicate with each other – also about possible complaints.*

***Sweden**: Before you approach IGN, you should have made an "cease request" to the concerned company. If that cease request is rejected/denied/no response, then you can file a complaint to IGN. IGN will then inform the other company. In certain, very limited cases, a company may request from IGN an exception (not to start with a "cease request") and if this is granted IGN will inform the other company concerned.*

***Norway**: There are no obligations to inform the other company before a company file complaint.*

***Finland**: Yes. A complaint can be brought to the Inspection Board unless the companies can agree on the case within seven business days from the first verifiable contact. The company can make a complaint earlier than this if it is impossible to agree on the dispute. The complaint with the*

Inspection Board must be made within 30 days from the first verifiable contact, on pains of the case becoming void. Under exceptional circumstances, however, the companies can verifiably agree to extend the 30-day deadline by the maximum of 14 days if the deadline for the complaint is July or if the company's first verifiable contact takes place in July.

***Iceland**: There are no obligation to inform the other company before a company file complaint.*

Q35: Do you need to report all activities (targeted HCPs) to the self-regulation board?

A: *This may differ from country to country.*

***Denmark**: Yes. Pharmaceutical companies are obligated to report activities aimed at HCPs to ENLI:*

a) which are organised or co-organised by a pharmaceutical company, and the event is fully or partially directed against Danish healthcare professionals.

b) where a pharmaceutical company, without organising or co-organising the event, provides financial (sponsor) support to a so-called third-party event, fully or partially directed against Danish healthcare professionals or to the participation of Danish healthcare professionals.

c) where a pharmaceutical company buys an exhibition stand at a congress in Denmark.

d) In addition, pharmaceutical companies are obligated to report all kinds of printed promotion material aimed at healthcare professionals on the Danish market, whether in printed advertisements, leaflets, handouts or the like. Electronic texts are comparable with printed texts.

***Sweden**: Member companies are obliged to send all new promotion (including such invitations) as statuary copies to pliktexemplar@lif.se , see Article 31/131 (Chapter 1)*

***Norway**: Member companies are obliged to send copies of all Promotional materials, regardless of the format used by the business, to the Committee's Secretariat. Submissions are made electronically by uploading documents in the Secretariat's electronic archive.*

***Finland**: No, all TV and radio ads from member companies must go through a preliminary inspection. Otherwise the system is based mainly on complaints. Anybody can suggest cases to be handled.*

***Iceland**: No.*