

Guideline on Advertising, etc. of Medical Devices¹

1. Advertising rules

The rules on advertising of medical devices are found in Executive Order no. 1155 of 22 October 2014 on Advertising, etc. of Medical Devices (the Advertising Order).

2. Definition of advertising and scope of rules

2.1. Definition and scope

Advertising of medical devices means any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or use of medical devices, cf. section 1(2) of the Advertising Order.

The definition of advertising of medical devices is interpreted in a broad manner pursuant to the wording of the provision and the main purpose of the advertising rules, which is to protect human health.

The rules cover any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or use of medical devices.

The definition of advertising carries no criterion that the person advertising for a medical device must have a special, typically economic, interest in promoting the sale of the medical device. If a person or company via statements made in public aims clearly to induce others to buy a certain medical device, and such statements take the shape of advertising, this is by definition advertising of a medical device even if the person or company is acting on own initiative and is fully independent, de jure and de facto, of the medical device manufacturer.

The advertising rules apply to advertisements for medical devices, active implantable medical devices and in vitro diagnostic medical devices (in the following medical devices), cf. section 1(1) of the Advertising Order.

2.2. Exemptions

Not every piece of information about medical devices is covered by the rules on advertising of medical devices. The following list includes examples of information that is not advertising and thus not governed by the rules of the Executive Order on Advertising of Medical Devices.

- a) Label and instructions for use to the extent that the information does not contain information, images, illustrations, etc. of a promotional nature. If the label and instructions for use contain only the information which according to the executive orders on medical devices¹ must appear from the label and instructions for use, this would not constitute advertising of medical devices.
- b) Correspondence of an individual nature, if required accompanied by documents of a non-promotional nature, intended to answer a specific question about a certain medical device.
- c) Necessary and specific information or documentation that serves safety purposes, and not promotional purposes, e.g. information about changes to the packaging, new risks or manufacturing defects. The meaning

¹ Guideline no. 11357 of 29 December 2014 (Guideline on Advertising of Medical Devices)

of safety purposes is broad, implying that e.g. information on how to open a medical device package without damaging the medical device is also considered a safety purpose.

d) Informative material about health and disease, provided there is no direct or indirect mention of a specific medical device (a specific product). This could be anything from conventional leaflets to comprehensive internet websites.

e) Patient information folders provided by a doctor as part of prescribing treatment with a medical device. Patient information folders must contain only factual information of significance to the patient (and relatives) in connection with the use of a medical device. The information must not be inconsistent with the intended purpose declared by the manufacturer. Patient information folders will be considered as advertising if containing claims, information, images, illustrations, or the like which, wholly or mainly, serve promotional purposes.

f) Press releases that a) give factual and concise details about a medical device, b) are generally newsworthy, c) have the press as target audience, and d) which are distributed or made available to a multitude of reporters or media with a view to obtaining a journalistic assessment and examination prior to publication. A "press release" which appears as an advertisement because of subjective content, misleading information, exaggerations or strongly intrusive form, etc. will not be considered a press release. It will be considered as an advertisement for a medical device. If a "press release" is brought in a media against a fee, it will be considered as an advertisement for a medical device. A medical device manufacturer can make a press release available to the press in a press area on its website for about three weeks. After that, it will no longer be generally newsworthy, in which case it could be considered as advertising for a medical device based on an individual assessment.

2.3. Health professionals and other professionals

Part III of the Advertising Order provides special rules on economic advantages for health professionals and other professionals.

Health professionals mean doctors, dentists, veterinarians, pharmacists, nurses, pharmaconomists, midwives, bioanalysts, clinical dietitians, radiographers, social and healthcare assistants or students within these fields, cf. section 1(3) of the Advertising Order.

The rules on economic advantages from medical device companies also apply to owners of and managerial staff in shops that sell medical devices, and to medical device technicians and other persons who on a professional basis give advice about and purchase medical devices, including persons in the hospital sector, cf. sections 18 and 19 of the Advertising Order. For more information, see section 9.7.

A medical device company means manufacturers, distributors and importers of medical devices and their representatives, cf. section 1(5) of the Advertising Order.

For more information on the rules on economic advantages, see section 9.

3. General provisions

3.1. General advertising requirements

Section 2 of the Advertising Order lays down the general requirements for the content and form of advertising of medical devices. The provision applies to advertising of any type of medical device and any recipient of advertisements for medical devices.

3.1.1. Advertising of medical devices must be adequate

Advertising must be adequate, cf. section 2(1) of the Advertising Order. For instance, an advertisement must contain adequate information for recipients to understand and assess when and under which circumstances the medical device can and should be used, and when not to use it.

3.1.2. Advertising of medical devices must be factual

Advertising must be factual, cf. section 2(1) of the Advertising Order. Therefore, medical devices must not be marketed in the same aggressive and consumption-encouraging manner as general consumer goods. Furthermore, the advertisement must be based on professional and relevant information about the medical device. Whether an advertisement fails to be factual is determined by assessing the form and content in each specific case.

The following examples reflect advertisements which, upon individual assessment, may fail to provide factual information:

Advertising of medical devices that contain exaggerated claims about treatment. This could be advertisements that exaggerate the possibilities of treatment, thus creating unrealistic expectations in the patients.

The offering of gifts or competitions and prizes linked to the promotion of medical devices directed at patients and consumers.

Advertisements for medical devices containing spot prices highlighting great discounts and heavily reduced prices such as "buy now" offers that otherwise contain only little information about the product.

In regard to healthcare professionals, reference is made to the Advertising Order's section 9(3) on gifts, and section 10 on the prohibition against competitions and prizes, see section 9 below.

3.1.3. Information in advertisements must be consistent with the manufacturer's intended purpose.

The information given about a medical device in an advertisement must be consistent with the manufacturer's intended purpose and the scope of use of the medical device, cf. section 2(2) of the Advertising Order.

Advertising of medical devices must not contain information about intended purposes and uses that are inconsistent with the information the manufacturer has provided thereon.

3.1.4. Advertising of medical devices must not provide incorrect information.

Advertising of medical devices must not provide incorrect information, cf. section 2(3) of the Advertising Order. This means that advertising of medical devices must not provide incorrect information about the device, competing products, the manufacturer or competitors, etc.

The correctness of factual information must be supported by evidence, cf. section 3 of the Advertising Order, see section 3.2 below.

3.1.5. Advertising of medical devices must not provide misleading or exaggerated information.

Advertising of medical devices must not provide misleading or exaggerated information, cf. section 2(3) of the Advertising Order.

This means that the form and content of an advertisement must not lead its recipients to form misconceptions about the medical device, including its scope of use, benefits and risks, price, etc., disease or treatment. Nor must the advertisement put the product in a more favourable position than other corresponding and perhaps more suitable products.

An advertisement for a medical device must not, whether through form or content (the information provided), mislead or be designed to mislead its target audience or the persons it reaches.

Information must neither directly nor indirectly, whether through omissions, inaccuracies, ambiguities or through exaggerated claims, be designed to mislead its recipients. Misleading information could be information designed to fool or cheat the recipient or designed to lead the recipient astray.

3.1.6. Advertising of medical devices must not provide inadequate information.

Advertising of medical devices must not provide inadequate information, cf. section 2(3) of the Advertising Order, implying that information about medical devices, benefits and risks of treatment, prices, reimbursement, etc. must not be inadequate.

The information provided in an advertisement for a medical device could be inadequate if the information about the risks of using the device has been softened or significant risks have been omitted.

Likewise, an advertisement for a medical device could give inadequate information if it provides information about the price of a device, but fails to mention any extra charges, or if it fails to mention that the device can only be used together with other specific device accessory.

3.2. Duty to provide supporting evidence

The correctness of factual information must be supported by evidence, and the party responsible for the advertisement must, on request of the Danish Health and Medicines Authority, present this evidence to the Authority, cf. section 3 of the Advertising Order. This applies to any factual information given in the advertisement.

4. Comparative advertising

If an advertisement includes a comparison of medical devices, it must be clear which medical devices are being compared. Comparisons are only allowed for medical devices that are relevant to compare from an objective point of view, i.e. medical devices with the same scope of use, cf. section 4 of the Advertising Order.

An advertisement that makes a comparison, including a price comparison, will generally only be adequate if it covers all corresponding products with the same scope of use, cf. section 2(1) of the Advertising Order. A medical device with an insignificant market share can nonetheless be excluded from the comparison. A market share of up to 2-3 % is generally considered as insignificant.

The correctness of the factual information provided in the comparison must be supported by evidence, cf. section 3 of the Advertising Order.

5. Prohibitions

General prohibitions

Section 5 of the Advertising Order includes prohibitions that apply to advertising of all types of medical devices to any recipient of advertisements for medical devices. Advertising of medical devices must not:

- 1) give the impression that it is unnecessary to consult a doctor, dentist or other persons who use the device as part of their profession if the treatment or diagnosis by such person is relevant,
- 2) give the impression that using the medical device is without risk,
- 3) give the impression that the general health could deteriorate by not using the medical device,
- 4) be directed exclusively or principally at children,
- 5) be such that it might lead to erroneous self-diagnosis, or
- 6) use, in exaggerated, alarming or misleading terms, images, illustrations, etc. of changes in the human body caused by disease or injury, or of the effect of the medical device on the human body or parts thereof.

The prohibition against giving the impression that using the medical device is without risk, cf. section 5(ii) of the Advertising Order, implies that it is not allowed in advertisements for medical devices to say that the device is "without risk", "safe" or "without adverse reactions" or to use similar claims. The party responsible for an advertisement for a medical device can leave out the mention of risks in the advertisement if the device has no known risks.

The prohibition against giving the impression that the general health could deteriorate by not using the medical device, cf. section 5(iii), implies, for example, that it is not permitted to give the impression that not using the device could cause sadness, tiredness or depression or reduce life quality.

Advertisements for medical devices must not be directed exclusively or principally at children, cf. section 5(iv) of the Advertising Order. To illustrate, it is not permitted to advertise for medical devices on a website for children or in a children's magazine. Nor is it permitted to address children directly in an advertisement for a medical device. Due to their lack of experience, children must be assumed to be highly susceptible to advertising, which is why advertising of medical devices must not be directed exclusively or principally at children.

5.2 Special prohibitions in regard to advertising of medical devices to persons who do not on a professional basis purchase, distribute or use the devices – advertising to consumers, etc.

Section 6(1) of the Advertising Order contains a number of special prohibitions that apply to advertising to persons who do not on a professional basis purchase, distribute or use the devices being advertised.

Pursuant to section 6(1), advertising of medical devices aimed at persons who do not as part of their profession purchase, distribute or use the device being advertised must not

- 1) include recommendations by scientists, health professionals or other persons, associations of persons, institutions, companies, etc. whose prestige or the like in the health area could encourage the use of medical devices,
- 2) mention, directly or indirectly, serious diseases, cf., however, sections 7 and 8, or
- 3) refer to studies, literature, journals, etc.

These prohibitions thus apply to advertising to the general public, including advertising to consumers.

5.2.1 Recommendations by persons of particular prestige

The prohibition against using persons, etc. of particular prestige or the like, cf. section 6(1)(i), extends to persons whose prestige is conferred by their educational background, position, work or similar within the health area.

The term "prestige or the like." covers the prestige or respect that persons and associations of persons have because of their special status, specialist knowledge or expertise, e.g. health persons, scientists or professors within the health area.

The prohibition covers not only individuals, but also associations of persons, institutions, companies and the like. Therefore, just like a doctor must not advertise for medical devices, the same goes for hospitals or medical associations.

The "recommendation" referred to in the provision does not have to be express. The mere presence of persons, associations of persons, etc. of particular prestige in the form of a name or a picture will typically be considered a recommendation in itself.

The prohibition also covers the presence of a person in a white coat, etc. whom consumers would perceive to be a health professional, even though the person is really an (unknown) actor featuring in the advertisement. This person's outer appearance as health professional and recommendations could encourage the use of medical devices.

5.2.2 Serious diseases

To assess whether a disease is serious, cf. section 6(1)(ii) of the Advertising Order, a number of factors are taken into account, specifically whether the disease would typically require the assistance of a doctor, cause severe pain, lead to permanent deterioration in health, confine the person to bed, lead to incapacity or could potentially shorten the person's life or reduce life quality. Examples of serious diseases include cancer, multiple sclerosis and epilepsy.

5.3.2. References to studies, literature, journals, etc.

The Advertising Order's section 6(1)(iii) contains a general prohibition against referring to studies, literature, journals, etc. in advertisements for medical devices aimed at consumers. Consequently, it is not allowed to refer to results of clinical investigations, non-interventional studies, laboratory tests or quality tests. Nor is it permitted to refer to articles published in scientific journals about results of clinical investigations of medical devices.

As mentioned in section 3.2, the party responsible for an advertisement must have evidence to support any factual information and must, on request, make this evidence available to the Danish Health and Medicines Authority, cf. section 3 of the Advertising Order. It is therefore assumed that the party responsible for the advertisement has evidence to support the information in the advertisement, and that evidence from studies, literature, journals, etc., is held available to the Danish Health and Medicines Authority.

5.3 Special medical devices intended for use by doctors or dentists

The Advertising Order prohibits the advertising of medical devices that are intended for the exclusive use of doctors or dentists in their treatment of patients to any other than doctors, dentists and persons who on a professional basis purchase medical devices, cf. section 6(2). It is a condition that the medical device according to the manufacturer is intended for the exclusive use by doctors or dentists. This could be surgical instruments and implants intended to be used only by doctors or dentists in the course of treating their patients.

6. Advertising of male and female condoms

Section 7 of the Advertising Order permits that advertisements for male and female condoms provide information that these methods offer protection against one or more of the sexually transmitted diseases listed in Schedule 1 of the Advertising Order. The sexually transmitted diseases appearing from Schedule 1 are AIDS, Chlamydia trachomatis, Gonorrhoea, Hepatitis B, Syphilis, Condyloma acuminata and Herpes genitalis. This is an exemption from the prohibition in section 6(1)(ii) of the Advertising Order. It is therefore permitted in advertisements for male and female condoms to inform consumers that these products offer protection against these diseases. It is presumed that the party responsible for the advertisement has evidence to support the information in the advertisement, and that the evidence is held available to the Danish Health and Medicines Authority. See section 3.2 above.

7. Advertising of dental care products

According to section 8 of the Advertising Order it is permitted in advertisements for dental care products covered by the rules on medical devices to indicate that using the dental care products may prevent 1) dental plaque, 2) caries (dental cavities), 3) gingivitis (inflammation of the gums) and 4) periodontitis (inflammation of the tissues surrounding the teeth). This is an exemption from the prohibition in section 6(1)(ii) of the Advertising Order. It is thus permitted in advertisements for dental care products covered by the rules on medical devices to inform consumers that these products may prevent these diseases. It is presumed that the party responsible for the advertisement has evidence to support the information, and that the evidence is held available to the Danish Health and Medicines Authority. See section 3.2 above.

8. Advertising on the internet

Advertising of medical devices on the internet must satisfy the same requirements as advertisements in other media. The rules apply to banner ads, internet advertising and the like which clearly take the form of advertising and to the mention of medical devices on e.g. the websites of medical device companies when such mention must otherwise be considered to fall under the definition of advertising, see section 2 above 'Definition of advertising and scope of rules'.

When it comes to internet advertising of medical devices intended for the exclusive use by doctors or dentists as part of treating their patients, access to the advertisement shall be restricted by means of a personal password, or some other efficient method, to doctors, dentists and persons who purchase the devices on a professional basis. It follows from section 6(2) of the Advertising Order that these products must not be advertised to anyone else than doctors, dentists and persons who purchase the devices on a professional basis. Efficient access restriction must therefore be secured to deny access by anyone else than doctors, dentists and persons who on a professional basis purchase the products. It is not sufficient that users can simply enter a password without access restriction to enter a web page. The minimum requirement is user identification by means of a unique user name, authorisation ID, or similar, linked with an individual password. It could be a special system used on the website in question or a general system, e.g. the user's digital signature. It is the party responsible for the advertisement who must efficiently secure that the web page is accessed only by doctors, dentists and persons who on a professional basis purchase the devices. The party responsible for the advertisement can inform the relevant persons about the access restriction, including that a password can be obtained by contacting the party responsible for the advertisement via the web pages open to the public. On Facebook, the party responsible for the advertisement can create a page that is closed to the public and give persons (doctors, dentists and purchasing agents) access on an individual basis. Anyone responsible for an advertisement should also be familiar with the rules in section 6 of the Danish Marketing Practices Act on unsolicited marketing purposes distributed to specific recipients by electronic mail. Reference is made to the Danish Consumer Ombudsman's guidance paper thereon.

9. Economic advantages for health professionals

According to section 9(1) of the Advertising Order, economic advantages must not be offered or given to health professionals for advertising purposes or otherwise to promote the sale of medical devices, cf. however subsections (2)-(4), sections 11, 13 and 16.

The prohibition in section 9(1) of the Advertising Order does not cover discounts on medical devices, cf. section 9(2) of the Advertising Order. A discount means a reduction in price. Section 9 applies to owners of and managerial staff in shops selling medical devices when the economic advantage concerns medical devices, cf. section 18 of the Advertising Order. They may also be awarded discounts in the form of purchase price reductions. Conversely, the prohibition in section 9(1) implies that it is not permitted to offer them economic advantages in the form of marketing fees or sales bonuses for selling medical devices. Also see section 9.7.

The prohibition in section 9(1) also does not cover gifts of insignificant value when the gift can be used in the recipient's business, cf. section 9(3) of the Advertising Order.

The provision makes it legitimate for medical device companies to offer gifts in kind to health professionals, provided the gift has insignificant value and can be used in the recipient's business. Both conditions must be met to make it legitimate to give or offer a gift. This also applies if the gift is a medical device (including samples).

The Advertising Order does not set an upper limit on the value of such gifts, but, if the total value from one giver to an individual health professional does not exceed DKK 300 in a calendar year, such gift(s) can be offered legitimately.

The value is not based on what the giver paid for the gift (he may have earned significant discounts through bulk buying), but on what the recipient would have to pay for a corresponding item under normal terms. In other words, it is the market value that determines the value of the gift.

Clinical thermometers, ball pens, mouse pads, calendars or desk pads are examples of gifts that »can be used in the recipient's business«. The same can be said for artwork, architect-designed lamps or radios, but these items fall outside the exception in section 9(3) even though they can well be placed in the health person's practice. The exception also does not cover gifts like wine, flowers or chocolate to health professionals on anniversaries or other special days, but covers gifts that can be used naturally in the course of the health professional's activities.

A gift that is financed significantly by a medical device company will generally be covered by section 9 of the Advertising Order, even when it seems to be given by a third party if the recipient should be able to tell that the company's involvement is decisive and required for the gift to be transferred to the recipient.

Section 9 of the Advertising Order extends also to »image gifts« from medical device companies to health professionals. It is thus irrelevant whether or not the gift is linked directly to the promotion of a certain medical device since it must be assumed that the company's interest in offering such economic advantages comes from intentions to promote not only the company but also its products. Consequently, image gifts are also considered to be given for purposes of advertising.

The prohibition in section 9(1) of the Advertising Order covers e.g. gifts in the form money (pecuniary gifts) to a health professional or a private association of health professionals, including professional societies. These type of gifts are not exempted in section 9(3). But special rules apply to the payment of direct expenses for hospitality in connection with advertising of and professional information about medical devices and payment of direct expenses for participation in relevant professional courses, conferences, training and the like, cf. section 13 of the Advertising Order and 9.4 below.

The prohibition in section 9(1) does not extend to the lending of medical devices for demonstration purposes to health professionals for maximum two months, cf. section 9(4) of the Advertising Order. This means it is permitted to make a medical device available to a health professional for a short demonstration period to allow the health person to decide if he or she wants to buy the device. Section 9(4) of the Advertising Order warrants the lending of medical devices to health professionals for demonstration purposes for maximum two months regardless of the value of the device. The exemption is limited to this period. Any lending of medical devices for a longer period

could well be an economic advantage of significant value which must not be given or offered to healthcare professionals for advertising purposes or otherwise to promote the sale of medical devices. Whether or not this is the case will be determined in the individual case based on the device's value, lending period, lending terms as well as the life span of the device.

The rules defining which gifts and other economic advantages that may be offered to health professionals are matched by a prohibition that health professionals must not receive or request to receive offers in breach of section 9(1), section 10 and section 11 of the Advertising Order, cf. section 12 of the Advertising Order.

9.1. Competitions

Section 10 of the Advertising Order prohibits competitions and prizes targeting health professionals for advertising purposes or otherwise to promote the sale of a medical device.

The prohibition of section 10 of the Advertising Order against competitions and prizes targeting health professionals is absolute, regardless of the nature of the competition or the value of the prize. It is irrelevant whether or not the competition held by a medical device company is linked directly to the promotion of a medical device. A competition launched at health professionals as part of a company's »image management« activities must be assumed to come from intentions to promote not only the company but also its products. Therefore, the competition must be assumed to have been conducted for advertising purposes in breach of the provision.

9.2. Remuneration for professional services

The prohibition against giving economic advantages to health professionals does not extend to the remuneration of the services of health professionals or pharmacies when such remuneration is proportionate to the service offered, cf. section 11(1) of the Advertising Order. Both the giver and recipient of remuneration must, on request, present the basis for determining the size of remuneration to the Danish Health and Medicines Authority, cf. section 11(1) of the Advertising Order. Remuneration under section 11(1) must be effected as a direct payment only and cannot take place through off-setting, transfer of benefits in kind or other indirect means, cf. section 11(2) of the Advertising Order.

Consequently, a health professional may receive payment for a service offered to a medical device company if the service is a natural element in an ordinary, mutually-binding agreement between the health professional and the company and if the service offered and consideration received in return are proportionate. One such example is the remuneration of a doctor for professional assistance to conduct a clinical investigation or the preparation of informative material about medical devices; another example is a remuneration fee to a health professional who participates on an advisory board; or a remuneration fee to a health professional who is to speak at a professional event. Whether payment and services are proportionate is determined on a case-by-case basis, taking into account the nature, duration and extent of the agreed service.

Doctors, dentists, nurses and proprietor pharmacists must apply for authorisation of or notify their affiliation with a medical device company to the Danish Health and Medicines Authority when they receive payment for a professional service under section 11(1), according to the rules of section 202A of the Danish Health Act and

Executive Order no. 1154 of 22 October 2014 on Health Professionals' Affiliation with Pharmaceutical Companies, Medical Device Companies and Medical Device Specialty Stores.

9.3 Payment for advertising space

A medical device company can pay for advertising space at a pharmacy. This could be a rental fee for window space to advertise for a medical device in a pharmacy, on a monitor in the pharmacy, advertisements in a pharmacy journal or similar. The rental fee for advertising space in a pharmacy must not exceed the market price for corresponding advertising space, and the fee must not be dependent on the pharmacy's sales of a medical device, cf. section 11(4) of the Advertising Order. Payment must be effected as a direct payment only, not through off-setting, transfer of benefits in kind or other indirect means, cf. section 11(2) of the Advertising Order. These rules also apply to fees paid for advertising space in any other retail shop selling medical devices, cf. section 18 of the Advertising Order.

9.4. Hospitality and sponsorship, etc.

The prohibition described in section 9 against giving or offering economic advantages to health professionals is modified by a number of explicit exceptions with regard to sponsorship and hospitality.

Notwithstanding section 9(1), section 13(1) of the Advertising Order allows the giving or offering of the below listed economic advantages to health professionals:

- 1) Hospitality in the form of payment of direct expenses for meals, travel, accommodation, etc. in connection with advertising of or professional information about medical devices, and
- 2) Professional information and training in the form of payment of direct expenses in connection with professionally relevant courses, conferences, supplementary training, etc. attended or conducted by health professionals. Included in these activities must be information about medical devices or other professionally relevant information of professional relevance to the participants.

The provision in section 13(1)(i) gives health professionals the opportunity of sponsorship of direct expenses for meals, travel, accommodation, etc. in connection with advertising of or professional information about medical devices. This also applies to hospitality in connection with participation in courses and other professional activities involving medical devices.

The provision in section 13(1)(ii) gives health professionals the opportunity of sponsorship of direct expenses for external and internal courses and other professional activities of professional relevance to the participants, e.g. course fee expenses, fees to external speakers or expenses to purchase course material.

The rules also apply if a medical device company specifically pays the direct expenses for a professionally relevant course, a professionally relevant conference, or the like, and any related hospitality expenses on behalf of a health professional employed at a hospital, even if it takes place under an agreement entered with the hospital or the region in the context of a call for tenders.

9.4.1. Level and extent

The services mentioned in section 13(1)(i) must be reasonable in level and must be strictly limited to the main purpose of the promotional or professional activity, cf. section 13(2) of the Advertising Order. This implies that events such as a full day seminar from 9:00 to 17:00 may include breakfast on arrival, lunch and possibly a light dinner to close the seminar. Such hospitality must not be offered to anyone else than health professionals, cf. section 13(2) of the Advertising Order. The spouse or cohabiter of a health professional may participate on a trip as part of an event covered by section 13(1)(i), provided the spouse or cohabiter pays for all expenses associated with his or her participation. Anyone who pays the expenses under section 13(1)(i) of a health professional must, on request of the Danish Health and Medicines Authority, present to the Authority information on the background for paying the expenses, cf. section 13(2) of the Advertising Order.

Likewise, anyone who pays the expenses under section 13(1)(ii) must, on request of the Danish Health and Medicines Authority, present to the Authority information on the background for paying the expenses, cf. section 13(3) of the Advertising Order.

9.4.2. Events held abroad

If promotional or professional activities are held abroad, the benefits mentioned in section 13(1) may only be paid if the reason for having the event abroad is justified in substantive, practical or financial circumstances of significance, cf. section 13(4) of the Advertising Order.

This would apply if, for example, it is considerably cheaper to send a group of health professionals to an event abroad than it would be to set up a similar event at home.

The circumstances of significance that justify holding an event abroad must, on request, be presented to the Danish Health and Medicines Authority, cf. section 13(4) of the Advertising Order.

9.4.3. Notification to the Danish Health and Medicines Authority

Health professionals must notify the Danish Health and Medicines Authority if they receive payment for expenses under section 13(1) in connection with participating in professional activities abroad. Notification must be submitted electronically using a form placed on the website of the Danish Health and Medicines Authority, cf. section 14(1) of the Advertising Order.

The notification must include the following details: 1) identification of the health person, 2) identification of the company having paid the expenses pursuant to section 13(1), 3) identification of the organiser of the professional activity if this is not the company having paid the expenses pursuant to section 13(1), 4) information about the professional activity, and 5) the end-date of the activity, cf. section 14(2) of the Advertising Order.

The information mentioned in section 14(2) is published on the website of the Danish Health and Medicines Authority and will be deleted from the website two years after the activity ended, cf. section 14(3) of the Advertising Order.

When a medical device company promises a health professional to pay the expenses under section 13(1) for that person's participation in professional activities abroad, it must make the person aware of the rules in section 14 of the Advertising Order and sections 202B and 202C of the Danish Health Act, including the person's duty to notify the Danish Health and Medicines Authority and the Authority's publication of information about the affiliation, cf. section 15 of the Advertising Order. This information can be given orally or in writing.

The same applies to persons, covered by sections 18 and 19 of the Advertising Order, if they receive payment for the expenses mentioned in section 13(1) in connection with participation in professional activities abroad.

9.5 Public meetings

Medical device companies are permitted to sponsor meetings that provide professional information about medical devices to the public hosted by health professionals and pharmacies, cf. section 16(1) of the Advertising Order. Such events may also include information about health and disease.

The amount paid in sponsorship must not exceed the direct expenses related to the hosting of the event in question, cf. section 16(2) of the Advertising Order.

A proprietor pharmacist who holds a professional information meeting at his own premises, can neither have his own fee nor the rental fee sponsored. However, the fee payable to an external speaker, costs for announcing the meeting and any additional costs for cleaning the premises can be sponsored legitimately.

Representatives from the sponsor company are not allowed to participate actively at the event, cf. section 16(2) of the Advertising Order. If a proprietor pharmacist was to host an information meeting about hypertension and measuring of blood pressure with a blood pressure meter and the meeting is sponsored by a medical device company that has a blood pressure meter in its product range, a representative from that company would not be allowed to discuss the company's product, hypertension, measuring of blood pressure or otherwise participate actively in the holding of the event.

Correspondingly, medical device companies may sponsor meetings that provide professional information about medical devices to the public hosted by owners of other shops that sell medical devices, cf. section 18 of the Advertising Order.

9.6 Entertainment

Medical device companies must not, for purposes of advertising, pay expenses for health professionals' participation in purely social or cultural events, cf. section 17(1) of the Advertising Order. This prohibition is broad and covers payment for tickets to theatre shows, museums, football matches or like activities. The prohibition applies regardless of the size of payment.

Nor must medical device companies arrange entertainment in conjunction with professional activities covered by section 13(1)(ii), cf. section 17(2) of the Advertising Order.

9.7 Persons in the business of selling, offering advice about and purchasing medical devices.

Sections 9-17 apply to owners of and managerial staff in shops selling medical devices when the economic advantage concerns medical devices, cf. section 18 of the Advertising Order.

Sections 9-17 apply to medical device technicians and other persons who on a professional basis give advice about and purchase medical devices, including persons in the hospital sector, cf. section 19 of the Advertising Order.

Persons who on a professional basis give advice about medical devices mean persons who on a professional basis offer professional advice about medical devices to municipalities, regions, the government, hospitals and other healthcare institutions. This could be medical device technicians, medical device engineers, advisers and other persons who offer professional advice about medical devices as part of their profession. The provision does not apply to medical device representatives employed by a medical device company. Persons who purchase medical devices mean persons who are employed to purchase medical devices, e.g. purchasing agents employed at hospitals, in regions, municipalities or self-governing institutions.

These persons are therefore equated with health professionals in regard to the rules on economic advantages, etc. in Part III of the Advertising Order. See sections 9-9.6 for further information about the provisions on economic advantages, etc.

9.8 Economic advantages for patient organisations

A patient organisation must publish on its website any economic advantages, including financial sponsorships (moneys) and payments in kind that the organisation has received from medical device companies, cf. section 20(1) of the Advertising Order. The information must be published such that the value of economic advantages is specified for each medical device company on the website, cf. section 20(2) of the Advertising Order. The information must be available on the website no later than one month after the patient organisation received the economic advantage and must remain available on the website for at least two years, cf. section 20(3) of the Advertising Order.

A patient organisation means an association of patients and relatives whose aim is to safeguard the interests of the patient group, cf. section 1(5) of the Advertising Order. A medical device company means manufacturers, distributors and importers of medical devices and their representatives, cf. section 1(4) of the Advertising Order.

10. Use of the word pharmacy

It follows from section 65 of the Danish Medicines Act that the word "pharmacy" must not be used in advertisements for non-pharmacy medicinal products or *products which are not medicinal products*, unless the party responsible for the advertisement can prove that the product is generally sold at pharmacies in Denmark. It is a provision that also applies to advertising of medical devices. If the party responsible for an advertisement can prove that the medical device is sold in more than half of the pharmacies in Denmark, using the word »pharmacy« is allowed. The requirement for the product to be sold in the majority of pharmacies must be satisfied at all times and provable to the Danish Health and Medicines Authority. The requirement for proof would generally be considered satisfied if an independent wholesaler confirms that the medical device is sold routinely to a majority of pharmacies.

11. Enquiries, complaints and legal recourse

11.1. Enquiries and complaints

Any questions and enquiries about the rules on advertising of medical devices and complaints about advertisements for medical devices should be sent to the Danish Health and Medicines Authority, Axel Heides Gade 1, 2300 Copenhagen S, Denmark, sst@sst.dk, see, however, section 11.2 below.

Anyone who complains about an advertisement generally cannot expect to remain anonymous because the complaint is governed by the rules on access to administrative files of the Public Administration Files Act and the Public Administration Act.

Decisions made by the Danish Health and Medicines Authority about advertising of medical devices can be referred to the Danish Ministry of Health, Holbergsgade 6, 1057 Copenhagen K, Denmark

11.2. Advertisements on radio and TV

Complaints about advertisements for medical devices on the radio and TV should be sent to the Radio and Television Board, Secretariat, Danish Agency for Culture, H. C. Andersens Boulevard 2, 1553 Copenhagen V, Denmark, post@kulturstyrelsen.dk.

The Radio and Television Board will obtain an opinion from the Danish Health and Medicines Authority before making a decision in cases about advertising of medical device.

12. Previous guideline

Guideline no. 10354 of 22 December 2014 on Advertising, etc. of Medical Devices is repealed.

Danish Health and Medicines Authority, 29 December 2014

Henrik G. Jensen

Official notes

¹Executive Order no. 1263 of 15 December 2008 on Medical Devices, Executive Order no. 1264 of 15 December 2008 on Active Implantable Medical Devices and Executive Order no. 1269 of 12 December 2005 on In Vitro Diagnostic Medical Devices.