Guideline no 9469 of 25 June 2024

Ministry of the Interior and Health

Further information

Guideline on Advertising, etc. of Medical Devices

1. Advertising rules

The rules on advertising of medical devices are provided in Danish Executive Order no 715 of 24 May 2022 on Advertising, etc. of Medical Devices (the Advertising Order); article 7 on the prohibition of misleading advertising in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices; and the corresponding article 7 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

Unless specified otherwise, any references in this guideline are to the Advertising Order.

The rules on advertising, etc. of products without an intended medical purpose are found in the Danish Executive Order no 838 of 20 June 2023 on Advertising etc. of Products without an Intended Medical Purpose. Read more about this in section 11 of this guideline.

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). The advertising rules apply to advertising of medical devices, active implantable medical devices and in vitro diagnostic medical devices (hereinafter referred to as medical devices), cf. section 1(1).

Whether something is advertising of medical devices is determined based on an assessment of the circumstances of each individual case, including the nature of the concerned activity carried out and the content of the message. The definition of advertising of medical devices is interpreted in a broad manner pursuant to the wording of the provision and the advertising rules' main purpose of protecting public health.

The rules on advertising of medical devices are not limited to certain senders or media. It is not a requirement that a message about a medical device must be disseminated in relation to commercial activities in order to be advertising. Nor is it a requirement that the person disseminating the message about a medical device is affiliated to the manufacturer having placed the device on the market. However, any affiliation to the manufacturer will be included in the assessment along with other circumstances, including the nature of the activity carried out and the content of the message.

If, for example, an employee of a medical device company shares or likes an advert for the company's medical devices, or shares or likes other material that contains claims or other positive mention of the medical device on a social media, this may be considered advertising of the product even if the person is acting on his own initiative. This assessment will be based on the nature of the activity carried out, the

content of the message, the employee's affiliation to the company and any other relevant circumstances. It is not a criterion that the material appears, in form, as typical advertising, e.g. an advert, since the definition of advertising is not restricted to certain formats, however, the assessment may include this along with other relevant circumstances. An advertisement that both promotes the company and one of its medical devices will also be treated as an advertisement that must conform to the rules on advertising of medical devices. A company will not be considered responsible for an employee's action (advertising) on a social media if the company did not encourage such action or otherwise took part therein, and the action did not take place in a company context.

Influencers and bloggers may, depending on the circumstances, also be considered as the responsible senders of advertising of medical devices. Examples are influencers or bloggers who make claims about a medical device on a social media or an internet blog in connection with a review of the device or mention of the medical device company.

The definition of advertising carries no criterion that the person advertising for a medical device must have a special, e.g. 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 specific medical device, and such statements appear to be advertising, this will be considered as advertising of a medical device. It is irrelevant if the person or company is acting on their own initiative and is both legally and practically independent of the manufacturer of the device.

2.2. Exemptions

Not all types of information about medical devices are considered to be advertising of medical devices. The following list includes examples of information that is not advertising and thus not subject to the rules of the Advertising Order:

a) Label and instructions containing only the information required by the medical devices regulation[1], the in vitro diagnostic medical devices regulation[2] and the Danish executive order on medical devices[3]. The material must not contain information, pictures, illustrations, etc. of a promotional nature.

b) Correspondence of an individual nature, if required accompanied by documents of a non-promotional nature, intended to answer a specific question about a specific 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 of safety purposes is broad, implying that, for example, information on how to open a medical device package without damaging the medical device is also considered to serve a safety purpose.

d) Informative material on health and disease, provided that no reference, neither direct nor indirect, is made to a specific medical device (a specific product). This could be anything from conventional leaflets to comprehensive internet websites.

e) Patient information folders handed out by a doctor when prescribing treatment involving a medical device. Patient information folders must contain no other than factual information of significance to the patient (and possibly their relations) in connection with the use of a medical device. The information must not be inconsistent with the manufacturer's intended purpose. Patient information folders will be

considered advertising if containing claims, information, pictures, illustrations or the like that, wholly or mainly, serve promotional purposes.

f) Press releases that a) give factual and concise details about a medical device, b) are of general news value, 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" that appears as an advertisement due to factors such as subjective content, misleading information, exaggerations, or a strongly intrusive form will not be considered a press release but an advertisement for medical devices. If a "press release" is brought in a media against a fee, it will be considered advertising of medical devices. A medical device manufacturer may make a press release available to the press in a press area on its website for about three weeks. After this period, the press release will no longer retain its general news value, and following an individual assessment, it may be considered advertising of medical devices.

g) Employees of medical device companies sharing information about the company's medical devices on a social media for other than promotional purposes. For example, an employee might provide factual information about the device on LinkedIn to highlight their professional skills and share material of a non-promotional nature, such as a scientific article about a clinical investigation they were involved in.

h) Information about a medical device company, such as its participation in a healthcare conference or a debate on a current topic, provided the information contains no specifics about the company's medical devices and serves a purpose other than advertising of medical devices.

2.3. Healthcare professionals and other professionals

The Advertising Order distinguishes between advertising to the public and advertising to healthcare professionals.

'Healthcare professionals' means doctors, dentists, pharmacists, nurses, pharmaconomists, midwives, bioanalysts, clinical dietitians, radiographers, social and healthcare assistants and students within these fields, cf. section 1(3). Anyone other than these is considered the public.

However, there are a few exceptions in relation to persons who, although they are not healthcare professionals, handle medical devices as part of their profession. This concerns owners and managerial staff of retailers that sell medical devices, cf. section 19, i.e. professional groups with a decisive influence on the individual place of business.

This also concerns medical device technicians and other persons who, in the course of business, offer advice on medical devices and purchase medical devices, including persons in the hospital sector, cf. section 20.

Part III of the Advertising Order lays down specific rules on financial advantages for healthcare professionals and other professionals offered by, for example, medical device companies. A medical device company means manufacturers, distributors and importers of medical devices and their representatives, cf. section 1(4). Please see section 9 of this guideline for further details.

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 all types of medical devices and to all recipients (both the public and healthcare professionals) of advertising of medical devices.

3.1.1. Advertising of medical devices must be adequate

Advertising must be adequate, cf. section 2(1). For instance, an advertisement must contain enough information for the 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 of medical devices must be factual, cf. section 2(1). This means that 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 (non-exhaustive) examples reflect advertisements which, upon individual assessment, may fail to give factual information:

– Advertising of medical devices containing exaggerated claims about treatment. This could be advertisements that exaggerate the possibilities of treatment, thus creating unfounded expectations among patients.

– The offering of gifts or the holding of competitions and prize giveaways in conjunction with the promotion of medical devices to patients and consumers.

– Advertising of medical devices containing offers for free products, such as “three for two” to consumers, in which the price of two medical device packages is paid and one medical device package is supplied for free (as a gift).

– Advertising of medical devices containing flash offers that highlight great discounts and heavily reduced prices such as “buy now” offers that otherwise contain only little information about the product.

In relation to healthcare professionals, reference is made to section 9(3), which contains an exception for gifts, and section 10, which contains a prohibition against holding competitions and offering prize giveaways, cf. section 9 of this guideline.

3.1.3. Information in advertising must be consistent with the manufacturer’s intended purpose

The information provided about a medical device in an advertisement must be consistent with the manufacturer’s intended purpose and the relevant medical device’s field of application, cf. section 2(2).

An advertisement for a medical device must therefore not include information about the device's purpose and field of application that is inconsistent with the information provided by the manufacturer.

3.1.4. Advertising of medical devices must not contain false information

Advertising of medical devices must not contain false information, cf. section 2(3). Advertising of a medical device must therefore not contain false information about the device, competing products, the manufacturer or competitors, etc.

According to section 3, the correctness of factual information must be supported by documentation, cf. section 3.2 of this guideline.

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

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

Consequently, an advertisement must not, whether through form or content (the information provided), mislead or be designed to mislead its target audience or the persons it reaches.

A piece of information must neither directly nor indirectly, whether through omissions, incorrectness, ambiguities or exaggerated claims, be designed to mislead its recipients. Misleading information could be details having the potential to trick or deceive recipients or lead them astray.

Likewise, the form and content of the advertisement must not lead the recipients to form misconceptions about the medical device, including its field of application, benefits and risks, price, disease and treatment, etc. Nor must the advertisement put the product in a more favourable position than other corresponding and perhaps even more suitable products.

It follows from article 7 of both the medical devices regulation and the in vitro diagnostic medical devices regulation that, in connection with advertising, it is prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by:

– ascribing functions and properties to the device which the device does not have;

– creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;

– failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose; or

– suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.

3.1.6. Advertising of medical devices must not contain incomplete information

Advertising of medical devices must not contain incomplete information, cf. section 2(3). This means that the information provided about the medical device, benefits and risks of treatment, prices, reimbursement, etc. must not be incomplete.

An advertisement will be held to contain incomplete information if the information provided about the risks of the device has been played down, or essential information about risks has been left out.

This also applies if the advertisement fails to mention any extra charges or does not state that the device can only be used together with a specific accessory.

3.2. Obligation to provide documentation

The correctness of factual information must be supported by documentation, and the party responsible for the advertisement must, by order of the Danish Medicines Agency, make such documentation available to the Danish Medicines Agency, cf. section 3. This applies to any factual information given in the advertisement.

4. Comparative advertising

If an advertisement for a medical device includes a comparison with another medical device, it must be clear which devices are being compared. The comparison must only include medical devices that are relevant to compare from an objective point of view, i.e. medical devices that share the same field of application, cf. section 4.

An advertisement that makes a comparison, including a price comparison, will generally only be adequate, cf. section 2(1), if it covers all corresponding products with the same field of application. However, medical devices with an insignificant market share may be excluded from the comparison. A market share of (up to) 2-3% is generally considered insignificant.

The correctness of factual information included in the comparison must be supported by documentation, cf. section 3.

5. Prohibitions

5.1. General prohibitions

Section 5 of the Advertising Order contains prohibitions that apply to advertising of all types of medical devices and to all recipients of advertising of 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 professionally when 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 state of 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 incorrect self-diagnosis; or

6) use, in exaggerated, alarming or misleading terms, pictures, illustrations or the like 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), implies that it is not permitted to state in advertisements for medical devices that the device is, for example, “without risk”, “safe” or “without side effects”. The party responsible for an advertisement for a medical device may decide not to mention risks in the advertisement if the device has no known risks.

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

Advertisements for medical devices must not exclusively or principally be directed at children, cf. section 5(iv). Due to their lack of experience, children are considered highly susceptible to advertising. For this reason, advertisements for medical devices must not exclusively or principally be directed at children.

It is therefore not permitted to target children directly in advertisements for medical devices. Nor is it permitted to advertise for medical devices on a children's website or in a children's magazine.

5.2. Special prohibitions in relation to advertising of medical devices to persons other than those procuring, distributing or using the device in the course of business – advertising to consumers, etc.

Section 6(1) of the Advertising Order lays down a number of special prohibitions that apply to advertising to persons other than those procuring, distributing or using the advertised device in the course of business. These prohibitions thus apply to advertising to the public in general, including advertising to consumers.

According to section 6(1), this type of advertising must not:

1) include recommendations by scientists, healthcare professionals or other persons, associations of persons, institutions, companies or the like whose prestige or other standing in the healthcare area could encourage the use of medical devices;

2) directly or indirectly mention serious diseases, cf., however, sections 7 and 8; or

3) include references to studies, literature, journals or the like.

5.2.1. Recommendations by persons of particular prestige

The prohibition against using recommendations by 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 the like within the healthcare area.

The wording "prestige or the like" covers the prestige or respect that persons and associations of persons have because of their special status, knowledge or expertise. This could for example be healthcare professionals, scientists or professors in the relevant healthcare area.

The prohibition covers not only individuals, but also associations of persons, institutions, companies and the like. This means that, for example, a hospital or a medical association, just like a doctor, must not be used in advertising for medical devices.

The "recommendation" referred to in the provision does not have to be explicitly stated. The mere presence of persons, associations of persons, etc. of particular prestige, whether by means of their name or a picture, will typically be regarded as a recommendation in itself.

The prohibition also covers the presence of a person in a white coat or the like, whom consumers are likely to perceive as a healthcare professional, even though the person is really an (unknown) actor

featured in the advertisement. The individual's appearance as a healthcare professional, along with any recommendations made, could encourage the use of medical devices.

5.2.2. Serious diseases

The assessment of whether a disease is serious, cf. section 6(1)(ii), is based on a specific evaluation of criteria such as whether the disease typically requires medical consultation, causes significant pain, may lead to permanent health deterioration, necessitates bed rest, results in occupational disability, shortens life expectancy, or reduces quality of life. Examples of serious diseases include cancer, multiple sclerosis and epilepsy.

The Danish Medicines Agency may in extraordinary cases permit that serious diseases be mentioned if special health concerns speak in favour thereof, cf. section 6(3). The Danish Medicines Agency does not permit the mention of serious diseases in advertising on television, in films, in video or the like.

5.2.3. References to studies, literature, journals or the like

Section 6(1)(iii) of the Advertising Order lays down a general prohibition against making references to studies, literature, journals or the like in advertising of medical devices to consumers. For example, it is not permitted to make references to results of clinical investigations, performance studies, non-interventional studies, laboratory tests or quality tests. Similarly, referencing published articles from scientific journals on the results of clinical investigations of medical devices is not permitted.

As mentioned in section 3.2 of this guideline, the party responsible for the advertisement must be able to provide documentation for factual information and must, on request of the Danish Medicines Agency, make such documentation available to the Danish Medicines Agency, cf. section 3. It is thus assumed that the party responsible for the advertisement holds documentation for the information they provide in the advertisement, and that documentation from studies, literature, journals or the like is available to the Danish Medicines Agency.

5.3. Medical devices intended for use by doctors and dentists

Section 6(2) of the Advertising Order prohibits the advertising of medical devices that are intended solely for use by doctors or dentists in patient treatment to anyone other than doctors, dentists, or individuals responsible for procuring medical devices in the course of business. It is a condition that the medical device, according to the manufacturer, is intended only for use by doctors or dentists. This could be surgical instruments and implants that are intended solely for use by doctors or dentists in patient treatment.

6. Advertising of male and female condoms

According to section 7, it is permitted in advertising of male and female condoms to state that these devices offer protection against one or more of the sexually transmitted diseases listed in Annex 1 of the Advertising Order.

The sexually transmitted diseases listed in Annex 1 are AIDS, chlamydia trachomatis, gonorrhoea, hepatitis B, syphilis, condylomata acuminata and genital herpes. This is an exception to the prohibition laid down in section 6(1)(ii).

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 holds documentation for the information, and that such documentation is held available to the Danish Medicines Agency. Please see Section 3.2 of this guideline.

7. Advertising of dental products

Under section 8, it is permitted in advertising of dental products subject to the rules on medical devices to state that using the dental 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 exception to the prohibition laid down in section 6(1)(ii).

With respect to dental care products covered by the rules on medical devices, it is therefore permitted to state in advertising directed at consumers that the products can prevent these diseases. It is presumed that the party responsible for the advertisement holds documentation for the information, and that such documentation is held available to the Danish Medicines Agency. Please see Section 3.2 of this guideline.

8. Advertising on the internet and social media

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

In internet advertising of medical devices that are intended solely for use by doctors or dentists in patient treatment, access to the advertisement must, by means of a personal password or other efficient method, be restricted to doctors, dentists and persons who purchase the device in the course of business. It follows from section 6(2) that these products must not be advertised to anyone other than doctors, dentists, or individuals who procure medical devices in the course of business. Therefore, there must be an effective access restriction for persons other than doctors, dentists and those who procure the products in the course of business.

It is not sufficient if users need only enter a password without access control to enter a web page. The minimum requirement is user identification by means of a unique user name, authorisation ID, or the like, linked with an individual password. It could be a special system used on the web page in question or a general system, e.g. the user's digital signature.

It is the party responsible for the advertisement that must ensure efficient access restriction so that only doctors, dentists, and individuals who procure the device in the course of business can access the page. The party responsible for the advertisement may use a public area on its website to inform these persons about the access restriction and to instruct them to contact them for a password. On Facebook, the party responsible for the advertisement may 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 10 of the Danish Marketing Practices Act on unsolicited direct marketing targeted at specific recipients by means of electronic mail. Reference is also made to the Danish Consumer Ombudsman's guidance paper thereon.

9. Economic advantages for healthcare professionals

Section 9(1) provides that economic advantages must not be offered or given to healthcare professionals for promotional purposes or otherwise to promote the sale of a medical device. A number of exceptions apply in relation to gifts, payment for professional services, sponsorship and hospitality, etc. This is discussed in sections 9.1-9.8 below.

'Economic advantages' means, among other things, gifts in the form of money to a healthcare professional or a private association of healthcare professionals, including professional societies. The prohibition also covers image gifts from medical device companies to healthcare professionals. It is irrelevant whether or not the gift is linked directly to the promotion of a specific medical device since it must be assumed that the company's interest in offering such economic advantages comes from intentions to promote both the company and its products.

The rules specifying what gifts and other economic advantages may be offered to healthcare professionals are matched by a prohibition that healthcare professionals must not receive or request to receive benefits in breach of section 9(1), sections 10 and 11, cf. section 12.

9.1. Discounts

The prohibition in section 9(1) does not extend to discounts on medical devices, cf. section 9(2). 'Discounts' means a reduction in the price.

Owners of or managerial staff of retailers that sell medical devices are subject to section 9 when the economic advantage concerns medical devices, cf. section 19. They are permitted to receive a discount in the form of a reduction in the purchase price. In contrast, section 9(1) implies that it is not permitted, among other things, to offer the economic advantage in the form of marketing contributions or sales bonus for the sale of medical devices. Please also see Section 9.11 below.

9.2. Gifts

The prohibition in section 9(1) does not extend to gifts of insignificant value if the gift can be used in the recipient's line of business, cf. section 9(3).

The provision makes it legitimate for medical device companies to offer gifts in kind to healthcare professionals, provided the gift is of insignificant value and can be used in the concerned healthcare professional'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 a sample).

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 healthcare professional does not exceed DKK 300 in a calendar year, such gift(s) may be offered legitimately.

The value is not determined based on what the giver paid for the gift (they 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, the market value is used to determine the value of the gift.

Whereas gifts such as clinical thermometers, ball pens, mouse pads, calendars or desk pads can be used in the recipient's business, items such as artwork, architect-designed lamps or radios fall outside the exception rule in section 9(3) – irrespective of whether they are placed in the healthcare professional's practice. Similarly, the exception rule does not cover gifts like wine, flowers or chocolate given to healthcare professionals on anniversaries or other special days. The exception rule covers gifts that would be natural to use in the healthcare professional's business.

A gift that is financed significantly by a medical device company will generally fall under section 9 even when it appears to come from a third party, provided it is clear to the recipient that the company's involvement is a decisive and necessary condition for realisation of the gift.

9.3. Lending

The prohibition in section 9(1) does not extend to the lending of medical devices to healthcare professionals for demonstration purposes for up to two months, cf. section 9(4). It is therefore permitted to make a medical device available to a healthcare professional for a short demonstration period in order for the healthcare professional to decide whether or not to purchase the device. The exception applies irrespective of the value of the device, but is limited to the stated period of up to two months. The lending of medical devices for a longer period could be an economic advantage of significant value that must not be given or offered to healthcare professionals for promotional purposes or otherwise to promote the sale of a medical device. This will be determined on a case-by-case basis, taking into account the device's value, lending period, lending terms and lifetime.

9.4. Donation

The Advertising Order's rules on economic advantages to healthcare professionals do not apply to donations of medical devices to public healthcare institutions, regions, municipalities or private hospitals if the company (the private hospital) is not owned personally by a healthcare professional or a group of healthcare professionals (e.g. a sole proprietorship and partnerships).

9.5. Remuneration for professional services

The prohibition against offering economic advantages to healthcare professionals does not extend to the remuneration of the services of healthcare professionals or pharmacies when such remuneration is proportionate to the service offered, cf. section 11(1). Both the giver and recipient of remuneration must, on request, present the basis for determining the size of remuneration to the Danish Medicines Agency. 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).

Consequently, a healthcare professional may receive payment for a service offered to a medical device company, provided the service is a natural element of an ordinary, mutually-binding agreement between the healthcare professional and the company, and provided the service offered and consideration received in return are proportionate. One such example is when a doctor receives remuneration for professional assistance to conduct a clinical investigation or a performance study or for the preparation

of information material about medical devices. Another example is the remuneration of a healthcare professional who participates on an advisory board or speaks 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 Medicines Agency when they receive payment for a professional service under section 11(1), according to section 202A of the Danish Health Act and the Danish Executive Order on Healthcare Professionals' Affiliation with Medical Device Companies and Companies Manufacturing, Importing or Distributing Products without an Intended Medical Purpose and Medical Device Specialty Stores[4].

9.6. Payment for advertising space

A medical device company may pay for advertising space at a pharmacy. This could be rental fees for window space to promote a medical device in a pharmacy, on a monitor in the pharmacy, adverts in pharmacy journals or similar. The rental fee for advertising space offered by a pharmacy must not exceed the market price for corresponding advertising space, and the fee must not depend on the pharmacy's sales volume of a medical device, cf. section 11(4). The payment may only be made in the form of direct payment, not by set-off, transfer of goods in kind, or any other indirect method, cf. section 11(2). These rules also apply in relation to the payment of rental fees for advertising space at another retail outlet selling medical devices, cf. section 19.

A medical device company may also pay for advertising space made available by a professional society or an organisation consisting of healthcare professionals in connection with a professional event for healthcare professionals. This could for example be an annual conference organised by a professional society consisting of healthcare professionals. Such payment must be proportionate to the service offered (the advertising space), cf. section 11(1). This will be determined based on the number of participants at the annual conference, the duration and the price (market price) of corresponding advertising space. The payment must not exceed the market price for corresponding advertising space. A price per square metre of DKK 2,000[5], including VAT and administration fee, for a full-day event at a rented, external location accommodating about 50-80 participants would normally be considered proportionate to the service offered. A higher price per square metre can be accepted if the market price is higher due to a larger number of participants or other circumstances. Direct expenses that may be covered by a medical device company pursuant to section 13 cannot be included in the calculation of price per square metre for an exhibition booth. Professional societies must not, when calculating the price per square metre of an exhibition booth, include expenses such as remuneration paid to a speaker or meals paid to healthcare professionals.

9.7. Hospitality and sponsorship, etc.

Section 13(1) specifies that notwithstanding section 9(1), it is permitted to give or offer the below listed economic advantages to healthcare 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 healthcare professionals. It is required that information about medical devices or other professionally-relevant information of professional relevance to the participants is included in these activities.

The provision in section 13(1)(i) gives healthcare 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 courses and other professional activities involving medical devices.

The provision in section 13(1)(ii) gives healthcare professionals the opportunity of sponsorship of direct expenses for both internal and external courses and other professional activities of professional relevance to the participants. This may include expenses for course fees, fees for external speakers or expenses to buy course material.

These rules also apply if a medical device company specifically pays the direct expenses for a professionally relevant course, a professionally relevant conference and the like and expenses for hospitality in that regard for a healthcare professional employed at a hospital, even if it takes place according to an agreement entered with the hospital or the region in the context of a call for tenders.

9.7.1. Level and extent

The benefits 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). 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. The benefits must not involve anyone else than healthcare professionals, cf. section 13(2). The spouse or cohabiter of a healthcare professional may participate on a trip as part of an activity subject to section 13(1)(i), provided the spouse or cohabiter pays for all expenses associated with their participation.

Anyone who pays the expenses under section 13(1)(i) of a healthcare professional must, by order of the Danish Medicines Agency, present to the agency information on the background for paying the expenses, cf. section 13(2).

Likewise, anyone who pays the expenses under section 13(1)(ii) must, by order of the Danish Medicines Agency, present to the agency information on the background for paying the expenses, cf. section 13(3).

9.7.2. Events held abroad

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

It might be the case, for example, if it is considerably cheaper to send a group of healthcare professionals to an event abroad compared to organising a similar event in Denmark.

The substantial circumstances that justify holding an event abroad must, by order of the Danish Medicines Agency, be provided to the Danish Medicines Agency, cf. section 13(4).

9.7.3. Notification to the Danish Medicines Agency

Notification by healthcare professionals

Healthcare professionals must notify the Danish Medicines Agency if they receive payment for expenses under section 13(1) in connection with participating in professional activities abroad or in an international professionally-relevant congress or conference in Denmark. Notification must be submitted electronically using a form placed on the website of the Danish Medicines Agency, cf. section 14(1).

The notification must include the following details: 1) identification of the healthcare professional, 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).

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

When a medical device company has committed to covering the expenses under section 13(1) for a healthcare professional's participation in professional activities abroad or an international professionally-relevant congress or conference in Denmark, it must inform the person of the rules in section 14 and sections 202B and 202C of the Danish Health Act, including the obligation to notify the Danish Medicines Agency and the agency's publication of information about the affiliation, cf. section 15. This information can be given orally or in writing.

The same applies to the persons who are subject to sections 19 and 20 if they receive payment for the expenses mentioned in section 13(1) in connection with participation in professional activities abroad or an international professionally-relevant congress or conference in Denmark.

Further information is available in "Vejledning til sundhedspersoner, inkl. studerende og visse fagpersoner om anmeldelse af økonomisk støtte fra lægemiddelvirksomheder, medicovirksomheder og virksomheder, der fremstiller, importerer og distribuerer produkter uden et medicinsk formål" (Guideline for healthcare professionals, including students and certain professionals, on notification of financial support from pharmaceutical companies, medical device companies and companies manufacturing, importing and distributing products without an intended medical purpose).

Notification by medical device companies

By 31 January, medical device companies established in Denmark must notify the Danish Medicines Agency of the healthcare professionals and other professionals subject to sections 19 and 20 to whom they have provided financial support to attend professionally-relevant activities abroad and international professionally-relevant congresses and conferences in Denmark. The notification must include healthcare professionals and other professionals having received financial support in the preceding calendar year, cf. section 16(1). The notification must be submitted electronically using a form available on the website of the Danish Medicines Agency, cf. section 16(3).

The notification must include the following details: 1) The name and CVR number (central business registration number) of the medical device company, 2) the full name, email address, profession as well as authorisation ID or CPR number (civil registration number) of healthcare professionals and other professionals, and 3) information on professionally-relevant activities, cf. section 16(2).

A congress or conference held in Denmark will be considered an international congress or conference when several participants or speakers come from outside Denmark. Examples of international professionally-relevant congresses and conferences include international scientific congresses arranged by international professional scientific societies, or international professional conferences on specific therapeutic areas arranged by international organisations.

Further information is available in "Vejledning til lægemiddelvirksomheder, medicovirksomheder og virksomheder, der fremstiller, importerer og distribuerer produkter uden et medicinsk formål om økonomisk støtte til sundhedspersoner, inkl. studerende og visse fagpersoner" (Guideline for pharmaceutical companies, medical device companies and companies manufacturing, importing and distributing products without an intended medical purpose on financial support for healthcare professionals including students and certain professionals).

9.8. Public meetings

Medical device companies are permitted to sponsor meetings that provide professional information about medical devices hosted by healthcare professionals and pharmacies for the public, cf. section 17(1). Such events may also cover information about health and disease.

The amount paid in sponsorship must not exceed the direct expenses related to the hosting of the activity in question, cf. section 17(2).

If a proprietor pharmacist were to host a professional information meeting in their own premises, the proprietor pharmacist may neither have their own fee nor the rental fee sponsored. However, the fee for an external speaker, advertising costs and expenses for any additional cleaning of the premises may legally be sponsored.

Representatives of the sponsor company must not participate actively at the event, cf. section 17(2). If a proprietor pharmacist were to host an information meeting on hypertension and blood pressure measurement with a blood pressure measurement device, and the meeting is sponsored by a medical device company having a blood pressure measurement device in its product range, a representative of the company would not be permitted to talk about the company's product, hypertension, blood pressure measurement or otherwise actively participate in the event.

Correspondingly, medical device companies may sponsor public meetings that provide professional information about medical devices hosted by owners of other retailers that sell medical devices, cf. section 19.

9.9. Entertainment

Medical device companies must not for promotional purposes pay the expenses for healthcare professionals' participation in purely social or cultural events, cf. section 18(1). This prohibition is broad

and covers payment for tickets to theatre shows, museums, cinemas, 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 that are subject to section 13(1)(ii), cf. section 18(2).

9.10. Competitions

Section 10 prohibits competitions and prize giveaways directed at healthcare professionals for advertising purposes or otherwise designed to promote the sale of a medical device.

It is an absolute prohibition, 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 specific medical device. A competition launched at healthcare 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. Consequently, such competition will be assumed held for promotional purposes in breach of section 10.

9.11. Persons engaged in the sale, advisory services and procurement of medical devices

For owners or managerial staff of retailers that sell medical devices, the provisions in sections 9-18 apply if the economic advantage concerns medical devices, cf. section 19.

In the case of medical device technicians and other persons who, in the course of business, offer advice on medical devices and purchase medical devices, including persons in the hospital sector, the provisions of sections 9-18 apply, cf. section 20.

Persons who, in the course of business, provide advice on medical devices refers to persons who, in the course of business, offer professional advice on medical devices to municipalities, regions, the government, hospitals and other healthcare institutions, including private clinics. This could be medical device technicians, medical device engineers, consultants and other persons who offer expert advice on medical devices as part of their profession. The provision does not cover medical device consultants employed by a medical device company. Persons who purchase medical devices mean persons who are employed to purchase medical devices, i.e. procurement agents who work for hospitals, regions, municipalities, self-governing institutions or private clinics.

These persons are equated with healthcare professionals in regard to the rules on economic advantages, etc. in Part III. See section 9 of this guideline for further information about the provisions on economic advantages, etc.

9.12. Economic advantages received by patient organisations

A patient organisation must disclose 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 21(1). The disclosure must be made in such a way that the value of economic advantages is specified for each medical device company, cf. section 21(2). The information must be disclosed on the website no later than one month after the patient organisation received the economic advantage and must remain there for at least two years, cf. section 21(3).

‘Patient organisations’ means associations of patients and relations whose aim is to safeguard the interests of the patient group, cf. section 1(5). A medical device company means manufacturers, distributors and importers of medical devices and their representatives, cf. section 1(4).

10. Use of the word pharmacy

Under section 65 of the Danish Medicines Act[6], 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. This provision also applies to advertising of medical devices. If the party responsible for the advertisement can prove that the medical device is sold in more than half of the pharmacies in Denmark, use of the word pharmacy in the advertisement is permitted. The requirement for the product to be sold in the majority of pharmacies must be met at all times and documentation to that effect must be held available to the Danish Medicines Agency. The requirement for documentation will generally be considered satisfied if an independent wholesaler confirms that the medical device is sold routinely to a majority of pharmacies.

11. Advertising of products without an intended medical purpose

Certain products without an intended medical purpose are also regulated by the medical devices regulation and appear from an exhaustive list in Annex 16 of the regulation. Examples include equipment for liposuction, lasers for tattoo or hair removal or equipment for brain stimulation that apply electrical currents, etc. These products are also subject to a number of advertising rules specified in Danish Executive Order no 838 of 20 June 2023 on Advertising etc. of Products without an Intended Medical Purpose.

The rules concern gifts, competitions, professional services, hospitality and sponsorship, public meetings and entertainment and correspond to sections 9-20 of the Advertising Order as described in section 9 of this guideline. For products without an intended medical purpose, sections 9.1-9.11 of this guideline apply correspondingly.

12. Enquiries, complaints and legal recourse

12.1. Enquiries, complaints and legal recourse

Enquiries and complaints in relation to advertising of medical devices and products without an intended medical purpose may be submitted to the Danish Medicines Agency, Axel Heides Gade 1, 2300 Copenhagen S, Denmark, dkma@dkma.dk, see, however, section 12.2 of this guideline.

Please note that anyone who files a complaint about an advertisement cannot expect to remain anonymous as the report is subject to the provisions of the Danish Access to Public Administration Files Act and the Danish Public Administration Act.

Decisions made by the Danish Medicines Agency about advertising of medical devices and products without an intended medical purpose may be referred to the Department of the Ministry of the Interior and Health, Slotsholmsgade 10-12, 1216 Copenhagen K, Denmark, sum@sum.dk.

12.2. Advertisements on radio and television as well as via on-demand audiovisual media services

Complaints about advertisements for medical devices on the radio and TV as well as via on-demand audiovisual media services [7] may be submitted to the Danish Radio and Television Board, Agency for Culture and Palaces, Hammerichsgade 14, 1611 Copenhagen V, post@slks.dk.

The Radio and Television Board will obtain an opinion from the Danish Medicines Agency before a decision is made in cases involving advertising of medical devices.

13. Previous guideline

Guideline no 11357 of 29 December 2014 on Advertising of Medical Devices is repealed.

Danish Medicines Agency, 25 June 2024

Official notes

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

[2] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices

[3] Danish Executive Order no 837 of 20 June 2023 on Medical Devices etc.

[4] Danish Executive Order no 879 of 28 June 2024 on Healthcare professionals' Affiliation with Pharmaceutical Companies, Medical Device Companies and Companies Manufacturing, Importing or Distributing Certain Products without an Intended Medical Purpose and Medical Device Specialty Stores.

[5] 2022 level

[6] Danish Medicines Act, cf. Consolidation Act no 339 of 15 March 2023

[7] An on-demand audiovisual media service is defined in the Danish Radio and Television Broadcasting Act as an audiovisual media service offered by a media service provider for the viewing of programmes at a time chosen by the user and at the request of the user on the basis of a catalogue of programmes selected by the media service provider, cf. section 2(3) of the Danish Radio and Television Broadcasting Act, etc., cf. Consolidation Act no 1350 of 4 September 2020.