

Guidance on advertising etc. for medicinal products

1. Advertising regulations

The regulations on advertising medicinal products are to be found in Medicines Act, Chapter 7(s. 63-70), Order No. 272 of 21st March 2007 on advertising etc. for medicinal products¹⁾ (Advertising Order) and Order No. 1244 of 12th December 2005 on supply of medical samples.

Further, the Medicines Act s. 71a-71c and Pharmacies Act s. 3b contain rules on bonuses and discounts given in trading pharmacy-only medicinal products. These rules and regulations are also referred to in this guidance.

2. Applicability of the concept of advertising and regulations

2.1. Definition and scope

The concept of advertising in medical legislation is defined in Advertising Order s. 1(1). Advertising for medicinal products shall be taken to mean any kind of active information process, searching for customers or influencing opinions aimed at promoting the prescription, supply, sale or use of medicinal products.

In the definition of advertising, it is not a criterion that the person advertising a medicinal product is required to have a special, typically a financial, interest in promoting the sales of the medicinal product. If a person or company makes public statements which are clearly aimed at influencing other people to buy a specific medicinal product and such statements appear as advertising, this would indicate medicinal product advertising even though the persons or companies were acting on their own initiative and are legally and actually completely independent of the holder of the marketing authorization for the medicinal product.

The advertising regulations apply to all types of medicinal product for animal and human use, also including homeopathic remedies, traditional herbal remedies and natural remedies and high strength vitamin and mineral substances except for the few exceptions allowed in the Medicines Act and Advertising Order.

2.2. Exceptions

According to s. 2, the following information, etc., falls outside the scope of the advertising regulations:

- 1) Labelling of the medicinal products and patient information leaflets, cf. Order on Labelling etc. of medicinal products.
- 2) Correspondence of an individual nature, if necessary accompanied by documents not intended for advertising purposes, which serve to respond to a specific query about a specific medicinal product.
- 3) Specific, essential information or documentation that serves safety-related, non-advertising purposes. This might for example be information about changes to packaging, new risks of side-effects or production faults. Safety purposes should be construed widely so that for example information about how drug packaging should be opened to prevent its being physically damaged also serves a safety purpose within the meaning of the phrase in the Advertising Order.
- 4) Price lists, product catalogues, etc. not containing information about medicinal products apart from their names and prices. Publications shall not include information on competing medicinal products.

- 5) Information matter about health and disease, provided that there is no direct or indirect mention of specific medicinal products. This might be anything from traditional folders to extensive Internet websites.
- 6) Patient information leaflets provided by the issuer of a prescription as part of prescription for a medicinal product or by the pharmacy when supplying a medicinal product, and which only contain objective information of importance to patients and their relatives. The information given in the leaflet must not conflict with the product summary.
- 7) Press releases which contain summary information about a medicinal product, have general news value, are aimed at the media as a target group and which are sent to or made available to a majority of journalists or media with a view to journalistic assessment and consideration before publication. In contrast, if a press release on a medicinal product is put on a company website that is publicly accessible and if it is designed to promote the prescription, supply, sale or use of a certain medicinal product, it will be covered by the advertising regulations.
- 8) An unedited and unabbreviated reproduction of officially approved information about a medicinal product by way of a patient information leaflet, product summary or publicly available evaluation report on condition that the information is made available in such a way that users need to actively search for the information. This means for example that a company can put a list of the names of its medicinal products on its website with links to the product summary and patients leaflet for each individual medicinal product.

Information material on medicinal products drawn up by public medicine committees is intended to promote rational drug usage and is not covered by the advertising regulations. It is also not regarded as advertising when pharmaceutical companies send out scientific articles on clinical trials of medicinal products to healthcare personnel provided that the articles are sent without comment and without supplementary documentation. Articles must have already been published in a recognized, independent Danish or international journal, etc. This also applies for scientific articles containing results of comparative studies of various medicinal products sent out without comment.

2.3 Healthcare personnel and the general public

The advertising regulations differentiate between advertising to the general public and advertising to healthcare personnel. Healthcare personnel are taken to mean doctors, dentists, veterinarians, pharmaceutical chemists, nurses, veterinary nurses, pharmaceutical economists and students of these subjects, cf. Advertising Order s. 1(3).

All persons other than these healthcare personnel are regarded as the general public, cf. Medicines Act s. 66(2) and Advertising Order s. 1(2). There are however some exemptions from this with respect to persons who, without being healthcare personnel, are engaged commercially in medicinal products, for example store personnel who do not sell pharmacy-only medicinal products, cf. Advertising Order Chapter 8. See section 4.6 for more details.

3. General provisions

3.1. Basic requirements for advertisements

s. 63 Medicines Act gives the basic requirements for the content and design of medicinal product advertising. These provisions apply to advertising to the general public as well as advertising to healthcare personnel.

First, advertising must be adequate. This means that it is not sufficient for an advertisement not to contain incorrect or misleading information. An advertisement must contain sufficient information to enable the recipient of the advertisement to understand and assess when and in which situations medicinal products can and should be used and when they should not be used.

For example, an advertisement is inadequate if it contains such broad statements that it is aimed at promoting use of a product which is in fact not an especially appropriate drug to use in the particular situation.

The provisions that an advertisement should contain a certain amount of so-called mandatory information, cf. secs. 4.4 and 5.1, are based on the requirement for medicinal product advertising to be adequate.

Secondly, advertising must be objective. This means that medicinal products must not be marketed in such an aggressive and consumption-stimulating way as ordinary consumer goods. Medicinal product advertising should not aim, or be suited, to stimulate unnecessary additional use of medicinal products.

Thirdly, advertising must not be misleading or exaggerate the properties of medicinal products. This means that the design and content of the advertisement must not give users of medicines or persons who prescribe or supply medicinal products, an erroneous perception of the medicinal product, including its efficacy, side-effects, price, content, etc. The advertisement must also not place the medicinal product in a more favourable light than other comparable and possibly even more suitable medicinal products.

Fourthly, the information in the advertisement must be in accordance with the medicinal product's approved product summary. The product summary contains, *inter alia*, information about the composition of the medicinal product, its form, indications (applications), contra-indications, side-effects, precautionary measures, dosage and any warnings.

This means that the actual content of the advertisement must not conflict with the content of the product summary. But it is possible, within the bounds of objectivity, to use other wording than in the product summary.

3.2 Comparative advertising

If an advertisement contains a comparison of several medicinal products, including a price comparison, it shall be clearly stated which medicinal products are covered by the comparison, including their strengths, pack sizes, etc. Advertising Order s. 16(1).

Comparisons shall only cover medicinal products, including their strength and pack sizes, where comparison is objectively relevant, i.e. medicinal products with identical areas of application, cf. Advertising Order s. 16(1).

A comparison is only adequate in accordance with Medicines Act s. 63 if it covers all synonymous medicinal products (and any parallel imports) with the same packaging or product form or strength or where the pack size is not significantly different. Medicinal products with an insignificant market share may be omitted from comparisons.

Comparative advertising must in accordance with s. 16(2) always be done on the basis of the information given in the product summaries for the medicinal products covered by the comparison.

Since it is prohibited pursuant to s. 10(1.2) to give the general public an impression that the efficacy of a medicinal product is better than or just as good as that of another medicinal product, comparisons of the efficacy of several medicinal products must not be made in advertisements to the general public cf. Advertising Order s. 16(3).

3.3. Medicinal products not sold in Denmark

According to Medicines Act s. 64(1), medicinal products which must not be lawfully traded or supplied in Denmark must not be advertised.

A new medicinal product can only be lawfully traded from the date of grant of a marketing authorization. If a pharmacy-only medicinal product is involved, it is also a condition that the party putting the medicinal product on the market in Denmark shall have submitted a price for the medicinal product to the Danish Medicines Agency at least fourteen days before the effective date of the price, cf. Medicines Act s. 77(1). For certain non-pharmacy-only medicinal products, it is a requirement that fourteen days' notice of the pack sizes in which the medicinal products are traded shall also have been reported to the Danish Medicines Agency, cf. Medicines Act s. 78(1).

3.4. *Ex tempore medicinal products*

According to Medicines Act s. 64(2), *ex tempore* medicinal products must not be advertised. This provision is a natural consequence of the fact that *ex tempore* medicines are made up individually for an individual patient or animal on the instructions from a doctor or veterinarian.

3.5. *Special medicinal products*

According to Advertising Order s. 3(3-5), it is not possible to advertise:

- Medicinal products for non-clinical or clinical trials when marketing authorizations for the medicinal products have not been issued
- Medicinal products sold or supplied under a special permit pursuant to Medicines Act s. 29, and
- Sera, vaccines, specific immunoglobulins and other immunological test substances not covered by a marketing authorisation, which are sold or supplied by the National Serum Institute or the Veterinary Institute at Denmark's Technical University pursuant to Medicines Act s. 30.

3.6. *Retention of advertisements*

According to Medicines Act s. 68(1-2), the holder of a marketing authorisation for a medicinal product shall retain a copy of, or other documentation for, all advertisements for the medicinal product for at least two years. During this time, the holder of the marketing authorization must keep a copy of all advertising matter regardless of the form in which it was displayed. The material must be made available to the Danish Medicines Agency on request.

According to s. 17(2), advertising material must be retained in printed form or digitally in a standard format. This means that a printed advertisement may be retained either on paper or similar fixed medium or digitally. Even though an advertisement has been printed in several journals, hung as posters or sent out as folders or the like, there is no requirement for a paper version to be retained.

A standard digital format shall be taken to mean formats (file types) that are commonly used in Denmark and which normally do not cause problems when displaying file contents on a PC or when being shared by several parties. Examples could be the PDF (Portable Document Format; suffix:.pdf) presentation format and TIFF (Tagged Image File Format; suffix:.tif or.tiff) and JPEG (Joint Photographics Expert Group; suffix:.jpeg or.jpg) image display formats.

Apart from the actual advertisement, the holder of the marketing authorization is required to retain details of how the advertisement was used in practice cf. 17(3.) Advertising Order.

- 1) The target group for the advertisement, that is the persons at whom the advertisement was directed
- 2) Distribution system
- 3) A schedule of the media where the advertisement was displayed
- 4) The dates when the advertisement was used

If a party other than the holder of the marketing authorization advertises a medicinal product, the duty to retain the advertisement, etc., resides with the other party which thus becomes responsible for the advertisement. This might for example be a retailer or a parallel distributor.

According to s. 68(4) Medicines Act, the Danish Medicines Agency may require all necessary information to be provided by the party who is responsible for an advertisement so as to check that the advertising is lawful.

This provision makes it possible for example for the Danish Medicines Agency to demand specified information about the expenses of a pharmaceutical company for a trade congress so that they can check whether delegates at the congress have unlawfully received gifts or other financial benefits, cf. Advertising Order Chapter 7.

3.7. Order

The Danish Medicines Agency may pursuant to Medicines Act s. 69 require that unlawful advertising for a medicinal product be terminated.

The Danish Medicines Agency may further require the party responsible for the unlawful advertisement to publish a statement that the advertisement is to be stopped or to publish a justification for the advertisement. The Danish Medicines Agency decides as to the form and content of such publication.

3.8. Use of the word "Pharmacy"

The word "Pharmacy" may in general not be used in advertisements for non-pharmacy-only medicinal products, cf. Medicines Act s. 65. This refers amongst other things to certain OTC products, natural remedies, high strength vitamin and mineral products and a range of veterinary medicinal products.

If the party responsible for the advertisement can demonstrate that the medicinal product is traded at more than half of the country's pharmacies, use of the word "pharmacy" would however be permitted. The requirement for the medicinal product to be traded at a majority of the pharmacies must always be satisfied and this must be able to be demonstrated to the Danish Medicines Agency.

Pharmacies have an obligation to stock all pharmacy-only medicinal products, so use of the words "pharmacy" is always allowed in advertisements for such medicinal products.

4. Advertising to the public

4.1. Prescription medicines, etc.

According to Medicines Act s. 66(1), advertisements are not permitted to be directed at the general public for:

- 1) Prescription medicines.
- 2) Medicinal products that are unsuitable for use without the patient having been to the doctor to have an illness diagnosed or to have treatment monitored, i.e. medicinal products which should not be used and which it is not sensible to use without prior contact with a doctor.

Because of the provisions of (1) and the prohibition in s. 10(1.13), against mentioning serious disease, cf. sec. 4.5.2, this provision has a highly restricted independent area of relevance.

- 3) Medicinal products that are covered by the Euphorising Substances Act.

Because of the provisions of (1), this provision has a highly restricted independent area of relevance.

4.2. Trade journals

It is lawful to advertise prescription medicines in trade journals for healthcare personnel since advertising in such media is not regarded as advertising to the general public, even though by their nature, such magazines do get read to a certain extent by others than healthcare personnel. A magazine is regarded as a trade journal for health personnel if the majority of its content is professional and the majority of its readers and subscribers are healthcare personnel.

Pursuant to Medicines Act s. 66(3.), permission may be given to trade journals aimed at other than healthcare personnel to accept advertisements for prescription medicines. A reasoned application should be submitted to the Danish Medicines Agency by the trade journal concerned. When deciding whether to grant permission, the Danish Medicines Agency would take into consideration whether the target group has a special, acknowledged interest in the use and knowledge of prescription medicines. Depending on the circumstances, permission may be restricted to apply to certain types of medicinal product.

4.3 Concealed advertising

Advertising to the general public must be designed so that it is clear that it is an advertisement and that the advertisement relates to a medicinal product, cf. Advertising Order s. 4. The purpose of this

is to ensure that the persons at whom an advertisement is directed should be aware that it contains an advertising message and they can assess the message in that light.

In other words, any kind of concealed advertising for a medicinal product is forbidden. This might for example be the advertising camouflaged as the editorial in a journal, product placement of a medicinal product in a film or games on the Internet with an underlying advertising message.

4.4. Mandatory information

According to Advertising Order s. 5(1), an advertisement for a medicinal product must contain the information noted below in 1-8 (mandatory information), cf. however sec. 4.4.2-3 on special requirements for mandatory information in advertising in the open air, on film and the radio and on television, etc.

1) The name and generic name of the medicinal product.

The generic name is clearly determined as part of the approval process for a medicinal product and the generic name should give a clear indication of the product's content. This condition is not satisfied if the generic name is only, for example, given in a warning against misuse of the substance concerned.

2) Pack size.

All pack sizes must be given, cf. however sec. 4.4.4 on veterinary medicinal products.

3) Dated price (register price) incl. VAT and reference to the current price at www.medicinpriser.dk, if the product is pharmacy-only, cf. Medicines Act s. 60(1).

4) Efficacy, cf. Advertising Order s. 10(1.13).

The efficacy of the medicinal product must be stated in accordance with the product summary. If the formulation of the product summary is deemed to be difficult to understand for the ordinary medicine user, it could and should be rewritten in more understandable wording. Indications that the holder of the marketing authorization feels are irrelevant for the ordinary medicine user (or for special groups of medicine users at whom the advertisement is specifically directed), may be omitted. If the approved indications relate to serious diseases, they must not be mentioned, cf. s. 10(1.13) Advertising Order. See 4.5.2 for more details.

5) Side-effects

The side-effects mentioned in the product summary must fundamentally be included in the mandatory information. Side-effects that because of their rarity, nature or other objective criteria are deemed less important may, however, be omitted, and this should be decided by the holder of the marketing authorisation and not by others, for example chains of stores that do their own advertising for the medicinal product. The holder of the marketing authorization must at the request of the Danish Medicines Agency be able to account for why side-effects mentioned in the product summary have been omitted.

If a medicinal product has no side-effects, mention thereof must be omitted. For example "Side-effects: None" must not be stated, cf. Advertising Order s. 10(1.2).

6) Dosage.

Dosage must be stated in accordance with the product summary, although dosage exclusively for omitted indications, as above, must not be included.

7) An express request to read the information in the patient leaflet or on the packaging.

8) Other information that is required for correct and appropriate use of the medicinal product, such as warnings and possible reactions.

The holder of the marketing authorization must take a view as to what information needs to be included for users to get a correct and adequate picture of the medicinal product and its applications, cf. Medicines Act s. 63. The starting point should be the contraindications, special precautionary rules, interaction, relevant risks of over dosage, persistence and special warnings noted in the product summary which should be included in the advertisement. Information which objective criteria would indicate is irrelevant for disseminating to the general public may

be omitted. The holder of the marketing authorization must be able when requested to account to the Danish Medicines Agency as to why one or more details from the product summary have been omitted.

4.4.1. Advertising in the open air, on film and radio

According to Advertising Order s. 6, advertising in the open air, on film, including video film, and on the radio must contain the following information:

- 1) The name and generic name of the medicinal product. If the medicinal product contains more than one active agent, the generic name may be omitted, however.
- 2) Efficacy.
- 3) Significant side-effects
- 4) An express request to read the information in the insert or on the packaging.
- 5) An express request to contact a doctor (or veterinarian) or the pharmacy in cases of doubt.

4.4.2. Advertising on television

According to s. 7(1) Advertising Order, advertisements on television must contain the following information:

- 1) Name of the medicinal product.
- 2) Efficacy.
- 3) Significant side-effects
- 4) An express request to read the information in the insert or on the packaging.
- 5) An express request to read more about the medicinal product on the Text TV service of the television channel concerned and on the Internet. The holder of the marketing authorisation for the medicinal product shall publish all the information set forth in s. 5, on Text TV and the Internet.
- 6) The Text TV page number and the Internet address where the information given in (5) is published.

The information can either be given in easily legible text on screen or be spoken. However, the Text TV page and Internet address must also be given in text on screen, cf. Advertising Order s. 7(3).

4.4.3. On-screen advertising on shop premises

The regulations for advertising on television also apply to advertising on monitors (screens) in pharmacies and other stores selling medicinal products on condition that there is free access to the Internet from a PC, information stand or the like, on the pharmacy or the store premises, cf. Advertising Order s. 7(4).

Advertisements must include express information that there is free Internet access on the pharmacy or store premises and the Internet address at which further details of the medicinal product are available.

All information must be given in text on screen, cf. Advertising Order s. 7(5). Unlike TV advertising, it is not sufficient for mandatory information to be spoken.

The regulations on advertising for homeopathic medicinal products on monitors (on screen) in pharmacies or other stores selling homeopathic medicinal products, are regulated in Advertising Order s. 14(5).

4.4.4. Veterinary medicinal products

If a veterinary medicinal product is approved for use in several animal species, the mandatory information must basically contain information of the medicinal product's applications for all species.

If an advertisement is exclusively directed at people with a specific interests in a single animal species, the mandatory text can, according to Advertising Order s. 5(3), be restricted to information that is relevant for that specific species of animal.

For example, the mandatory text in an advertisement for a medicinal product that is approved for use in calves, cows, pigs, poultry, dogs and cats may be restricted in a journal for pig breeders to information about the product's applications in pigs; and in a brochure available at the pharmacy which is exclusively about treatments for dogs, to information about the product's canine applications.

If the mandatory text is directed in this way at an individual animal species, information that is irrelevant for the treatment of the species concerned must be omitted.

A brochure giving a general description of the efficacy of a medicinal product which is supplied to an unknown number of people, must contain the full mandatory text, that is information about the medicinal product's applications for all animal species.

4.4.5. Form requirements, etc.

All mandatory information must be presented (or be spoken) sufficiently clearly that the natural target group for the advertisement can have no difficulty in reading (or hearing and managing to comprehend) it, cf. Advertising Order s. 8.

When, as is most often the case, mandatory information is given in text, the height and thickness of letters as well as the contrast between the text and the background must be adapted to the circumstances under which the target group will be seeing an advertisement. Amongst other things, the distance at which the advertisement would typically be viewed and the lighting must be taken into consideration.

If an advertisement such as a window display consists of several components which make up an entity, it is not necessary to affix mandatory information to all the components. It is sufficient for the information to be affixed to a single separate component that forms part of the display on an equal footing with the other components.

4.5. Specific prohibition

s. 10(1) Advertising Order includes a series of specific restrictions as to what advertisements aimed at the general public may include. Advertisements must not:

- 1) Give the impression that consulting a doctor or veterinarian is superfluous,
- 2) Give the impression that the efficacy of the medicinal product is certain (guaranteed) and without side-effects or better than or just as good as the efficacy of another treatment, including another medicinal product,
- 3) Give the impression that use of the medicinal product can improve those in general good health,
- 4) Give the impression that those in general good health may suffer from not using the medicinal product,
- 5) Be exclusively or mainly directed at children,
- 6) Include a recommendation from healthcare personnel, researchers or other persons, associations of persons, institutions, companies, etc. who by virtue of their standing or the like may be used to promote the use of medicinal products, cf. 4.5.1,
- 7) Compare the medicinal product with foods, cosmetics or other consumer goods,
- 8) Give the impression that the medicinal product's safety or efficacy is due to the fact that the active ingredients come from nature,
- 9) Tend to lead to erroneous self-diagnosis,
- 10) Include exaggerated, frightening or misleading health statements,
- 11) Use visual portrayals of changes in the human body due to disease or lesions or the effect of a medicinal product on the human body or parts thereof, in an exaggerated, frightening or misleading way,

- 12) Include information that the medicinal product has been approved by the regulatory authorities,
- 13) Directly or indirectly mention serious disease or symptoms of serious disease cf. 4.5.2, or
- 14) Include references to studies, literature, journals, etc.

4.5.1. Recommendation from people of special standing

The prohibition against using persons, etc. who enjoy special standing or the like in Advertising Order s. 10(1).6) relates to persons whose standing derives from their education, work, etc. and those whose standing derives from their personal characteristics.

First, the concept of "special standing or the like" covers the standing or respect which people or associations of people may enjoy as a result of special knowledge or expertise. This might for example refer to healthcare personnel, researchers or professors.

Secondly, the concept covers the celebrity who has nothing to do with medicinal products, healthcare, etc. or the special status attaching to a specific profession. This might be either well known public figures such as actors, sports men and women and TV presenters or anonymous persons in especially prestigious jobs that give them authority, such as the police.

The prohibition does not only cover individuals but also associations of individuals, institutions, companies, etc. This means for example that just as a doctor or a celebrity football player may not be used in medical advertising, neither may a hospital or a football team.

The "recommendation" referred to in this provision does not need to be express. Merely the presence of persons, associations of persons, etc. with special standing by way of their name or image would typically be regarded as a recommendation *per se*.

The prohibition also covers the presence of someone dressed in a white laboratory coat or the like which consumers would perceive as someone in healthcare even though in the specific advert, it is an unknown actor. Such persons would by virtue of their appearance as healthcare personnel and recommendations be able to promote the use of medicines.

4.5.2. Serious disease

Assessment of whether a disease is serious, cf. Advertising Order s. 10(1.13), depends on a specific assessment of whether the emphasis is on the fact that the disease would typically require medical contact and treatment, give significant pain, lead to long term ill health, mean being bedbound or off work, shorten the lifespan or reduce quality of life.

In assessing what should be regarded as a symptom of a serious disease, the emphasis is on whether mention of the symptom directs the thoughts to a serious disease. There is no prohibition against mentioning a condition just because it could theoretically be a symptom of a serious disease.

4.6. Advertising to personnel in certain shops

When advertising to proprietors and employees in shops approved for the sale of non-pharmacy-only OTC products or non-pharmacy-only medicinal products for farm animals, the same provisions on mandatory information, reminders and information material apply as for healthcare personnel if the advertisement relates to such medicinal products. The provisions only apply, however, for employees dealing with the medicinal products mentioned above, cf. Advertising Order s. 28. For more details of the content of these provisions, see sec. 5.1-4.

The provisions on financial inducements, etc. in s. 21-27, s. 29 and s. 30 apply similarly to the proprietors and employees of stores approved for the sale of non-pharmacy-only OTC products and non-pharmacy-only medicinal products for farm animals. The provisions only apply, however, for employees dealing with the medicinal products mentioned above, cf. Advertising Order s. 28. Such persons must therefore be equated to healthcare personnel with respect to the rules on financial inducements, etc. in Chapter 7 of the Order. This means amongst other things that with respect to advertisements and trade information on these medicinal products, hospitality may be given or offered by way of payment for the direct expenses for meals, travelling, accommodation, etc., to

those covered by s. 28. For more details of the content of the provisions on financial inducements, etc., see secs. 5.5-5.7 and 6.

Proprietors of businesses approved for the sale of non-pharmacy-only medicinal products may not either give or offer hospitality to the general public as part of advertisements or trade information about medicinal products, cf. Advertising Order s. 20.

4.7. Hospitality

With respect to advertising medicinal products and trade information on medicinal products, no hospitality may be offered or given to the general public by way of payment of expenses for meals, travelling, accommodation, etc., cf. Advertising Order s. 20. This is an absolute prohibition, irrespective of the extent and value of the hospitality.

5. Advertising to healthcare personnel

5.1. Mandatory information

According to Advertising Order s. 11(1), advertising to healthcare personnel shall include the information (mandatory information) given in (1-11):

- 1) The name and generic name of the medicinal product. The generic name shall be given in the same lettering and in an equally prominent way as the medicinal product's brand name. For combination drugs without a generic name, clear information must be given about the generic names of all the active ingredients.

The same typeface means that it must have the same height, width, design and line thickness. It is, however, permitted to use different distances between the character for a brand name and a generic name, for example so that the letters in the generic name are written closer together than those in the brand name.

Brand and generic names shall be equally prominent. This is normally achieved by using the same colour and the same colour background for the names.

If a combination product is concerned for which there is no generic name, the generic names of the active ingredients need not necessarily be given in the same typeface as the brand name.

- 2) The name of the holder of the marketing authorisation.
- 3) The area of indication as stated in the product summary. In advertising exclusively directed at a restricted group of healthcare personnel, the statement of therapeutic indication area may be restricted to that which is relevant for the group concerned.

Basically, identical wording from the product summary should be used in the mandatory text. If the indications in the product summary are so extensive that it is thought inappropriate to repeat them in full, they may be rewritten and abbreviated. In so doing, information that is less relevant may be omitted.

Indications may under no circumstances be reworded in such a way as to lead to misunderstandings, including giving the impression that the scope of indications is different or broader than that set forth in the product summary.

If the wording of the product summary is not reproduced identically, it must be clearly so stated in the advertisement. It must further be clearly stated that the product summary may be obtained in its entirety from the holder of the marketing authorization. The following wording may be used:

"The indications section has been rewritten and/or abbreviated compared to the product summary approved by the Danish Medicines Agency. The product summary may be obtained free of charge from xx (the holder of the marketing authorization)". This information should be written in typeface that is larger than or in some other way clearly differs from the actual mandatory text. If information is missing, the advertisement is inadequate and thus not in conformity with Medicines Act s. 63.

- 4) Contra-indications.

Basically, the contra-indications included in the product summary should be included in the mandatory text. If the contra-indications in the product summary are so extensive that it is thought inappropriate to repeat them in full, they may be rewritten and abbreviated. In so doing, information that is less relevant may be omitted.

A view should be taken as to the precise delimitation of which contra-indications should be included and this should be done on the basis of objective criteria and take into account the requirements of Medicines Act s. 63.

If the contra-indications noted in the product summary are altered or their wording is changed, it shall be clearly so stated in the advertisement. It must further be clearly stated that the product summary may be obtained in its entirety from the holder of the marketing authorization. Reference is made to the wording proposed above for the indications section.

5) Side-effects and risks.

Basically, side-effects and risks, that is interactions, warnings, risk of overdosing, persistence, etc. contained in the product summary should be included in the mandatory text. If the choice of wording or extent of the formulation in the product summary makes it inappropriate for identical reproduction, the information may be rewritten or abbreviated.

Information that is regarded as less relevant in the given circumstances may be omitted.

If the wording of the product summary is not reproduced identically, it must be clearly so stated in the advertisement. It must further be clearly stated that the product summary may be obtained in its entirety from the holder of the marketing authorization. Reference is made to the wording proposed above for the indications section.

6) Dosage.

Dosage must be stated in accordance with the product summary. If the choice of wording or extent of the formulation in the product summary makes it inappropriate for identical reproduction, the information may be rewritten or abbreviated. Information that is regarded as less relevant in the given circumstances may be omitted.

If the wording of the product summary is not reproduced identically, it must be clearly so stated in the advertisement. It must further be clearly stated that the product summary may be obtained in its entirety from the holder of the marketing authorization. Reference is made to the wording proposed above for the indications section.

Rewording the dosage information requires great caution since any change in wording must not be able to lead to misunderstandings.

7) Authorised forms of the medicinal product.

Basically, all the forms in which the medicinal product is available shall be given. If a medicinal product has been approved in several medicinal product forms with different applications and the advertisement only refers to one of the forms of the medicinal product, the advertisement shall only include information about the particularly medicinal product form. It shall further be clear from the advertisement that the medicinal product is also available in other product forms. cf. Advertising Order s. 11(2).

Reference is made to sec. 5.2 for medicinal products designed for several animal species.

8) Pack size.

All pack sizes in which the medicinal product is available must be given. However, in instances where only some of the indications are included in the advertisement in line with the above, packs that cannot be used for the indications concerned should be omitted.

9) Dated price (register price) incl. VAT and reference to the current price at www.medicinpriser.dk, if the medicinal product is pharmacy-only, cf. however (4). The advertisement shall at the very least contain details of the retail price for individuals, cf. s. 2 of the Order on calculating consumer prices for pharmacy-only medicinal products and non-pharmacy-only OTC medicinal products, etc.

Insofar as it applies to the target group of the advertisement, the advertisement must give the price for supply to the institutions or persons given in s. 2(3-6) in the Order on calculating consumer prices for pharmacy-only medicinal products and non-pharmacy-only OTC medicinal products, etc.

Insofar as possible, the stated price must be current, i.e. applicable on the date on which the advertisement reaches the recipient, cf. Medicines Act s. 63.

The price may be omitted in advertisements displayed over a longer period, if a price list is appended instead and in advertisements with students as the only target group, cf. Advertising Order s. 11(4).

If the requirement for the statement of price is met by a regularly updatable price list, etc., being appended, the provisions on the statement of price are only satisfied if current prices are included or appended to the advertisement.

In some journals, advertisements have to be delivered a relatively long time before release date. It may therefore happen that it is not possible to meet the requirement for full price topicality. In such instances, some minor deviations from the prices actually applicable at publication date would be acceptable. How large such deviations could be depends on a specific assessment, but it would not be acceptable if the difference were to be such as to be significant for the user's choice of medicinal product.

If an advertisement contains price comparisons, the requirement for price topicality is normally regarded as unconditional.

10) Supply group.

11) Reimbursement status.

Advertisements must contain information about any general reimbursement for medicinal products.

In contrast, no information needs to be given about the possibility of being granted special individual reimbursement. If exceptionally it is thought to that information about individual reimbursement options should be given, for example individual reimbursement, it must be clearly stated that individual reimbursement is only obtainable on application.

All mandatory information must be so clearly presented that the natural target group for the advertisement can read it readily, cf. Advertising Order s. 11(5).

5.2. *Veterinary medicinal products*

If a veterinary medicinal product is approved for use in several animal species, the mandatory information must basically contain information of the medicinal product's applications for all species. If the advertisement solely refers to treatment of an individual animal species, the mandatory text can however be restricted to information about treatment of precisely that animal species, cf. Advertising Order s. 11(3).

In such case, the mandatory text should be targeted at the animal species concerned, i.e. information on irrelevant forms of the product or pack sizes should be omitted.

In cases where the mandatory text has been reduced to only deal with a single animal species, it must be clearly stated that the medicinal product is also approved for the treatment of other animal species. It should further be stated that information about all the animal species is available in the product summary which is obtainable on application to the holder of the marketing authorization. In default, the advertisement would be inadequate, cf. Medicines Act s. 63.

5.3. *Reminders*

An advertisement solely directed at healthcare personnel may be restricted so as only to contain the name and generic name of the medicinal product, cf. Advertising Order s. 12. This also applies if a pharmaceutical company publishes a product listing with the names of all medicinal products (without any form of comparison) for a specific area of treatment. If other information is included, such as prices, the advertisement would fall outside this clause and all mandatory information would

have to be included. The company name and logo identifying the publisher of the advertisement may be included, however.

5.4. Information material

According to Advertising Order s. 13, information material on a medicinal product sent or provided to healthcare personnel for sales purposes must at the very least contain the information given in Advertising Order 11(1), (mandatory information, cf. above) and the date the material was drawn up or most recently amended.

All information in the material must be precise, current, checkable and sufficiently extensive for the recipient to form a personal opinion as to the therapeutic value of the medicinal product, cf. Advertising Order s. 13(2). Citations, tables and illustrations taken from medical journals, scientific works, etc. used in the material must be reproduced faithfully and the precise source shall be given, cf. s. 13(3).

The product summary is regarded as the basic documentation on the properties of a medicinal product. Additionally, scientifically-based studies that have been published in recognized, independent works, trade journals, etc., may also be used according to Advertising Order s. 13(4). "Independent" shall be taken to mean that the party publishing the work or journal has no interest in the sale or any other form of promotion of medicinal products. Studies must have been subject to prior independent review.

So-called "abstract" and "data on file"²⁾ cannot be used as documentation since they do not satisfy the above requirements. "Data on file" that has been subject to independent review that is comparable with the assessment made prior to publication in a recognised scientific journal and which has been deemed reliable in the independent review, may however be used as documentation until comparable information has been published, or publication of the information has been rejected or new information has led to its scientific validity being revoked.

Reference may also otherwise be made to information at www.medicin.dk and the Institute for Rational Pharmacotherapy that has been subject to professional, independent review.

The fact that documentation material has been included in an application for approval of a medicinal product is not in itself sufficient for it to be used as documentation for information about said medicinal product.

5.5. Financial benefits for healthcare personnel

According to Advertising Order s. 21(1), no financial inducements may be given or offered to healthcare personnel for advertising purposes or otherwise to promote the sales of a medicinal product.

The prohibition does not cover gifts of insignificant intrinsic value or when given to mark a red-letter day for the recipient, such as a promotion or a special birthday, cf. Advertising Order s. 21(2).

In consequence, pharmaceutical companies may lawfully offer gifts by way of benefits in kind of insignificant intrinsic value if such gifts are associated with the business done by the healthcare personnel in the company concerned.

No upper limit on the value of such gifts is set in the Advertising Order but if the total value given to individual healthcare personnel does not exceed DKK 300 in a calendar year, the gift(s) would be regarded as lawful.

The value is not assessed on the basis of what the giver - who has possibly achieved a significant bulk buying discount - might have paid for the gift but what the recipient would have had to have spent for a comparable product if he/she had had to buy it ordinarily. Assessment of the value of a gift thus depends on its full retail value.

Gifts that "can be used in the recipient's business", might be medical thermometers, ball point pens, mouse mats, calendars or desk mats whereas artworks, designer lamps or radios, even though

they could be used in healthcare personnel's practices, cannot be said to be covered by the exemptions in s. 21(2).

Other "red-letter days" than those noted in s. 21(2) might be anniversaries, appointments, retirement, etc.

A gift that is significantly funded by a pharmaceutical company would fundamentally be covered by Advertising Order s. 21, even though actually given by a third party if it is obvious to the recipient that the company's input is a decisive, necessary precondition for the gift's being given.

s. 21 Advertising Order also covers "image gifts" from pharmaceutical companies to healthcare personnel. Accordingly, it does not matter whether the gift is directly associated with marketing a specific medicinal product since the company's interest in providing such financial inducements has to be assumed to be based on the desire to market the company and its products. Image gifts are accordingly deemed to be given for advertising purposes.

The regulations on gifts and other financial benefits that may be given to healthcare personnel are balanced by a prohibition against healthcare personnel requesting or receiving services that infringe Advertising Order s. 21(1), s. 22 and s. 23.

5.5.1. Competitions

The prohibition in Advertising Order s. 22 against holding competitions and prize draws for healthcare personnel is absolute. The nature of the competition and the value of prizes are irrelevant. It makes no difference whether a competition is being held by a pharmaceutical company in direct association with marketing a specific medicinal product. A competition for healthcare personnel as part of a company's "image care" is assumed to be based on the company's desire to market itself and its products. So a competition would also be deemed to be for advertising purposes and would infringe these provisions.

5.5.2. Payment for professional services

The prohibition against providing financial inducements for healthcare personnel does not cover payment for services from individual healthcare personnel or a pharmacy if the fees are commensurate with the service provided. At the request of the Danish Medicines Agency, both the giver and recipient of the fee are required to provide information on how the fee was determined, cf. Advertising Order s. 23(1).

Fees may only be paid in money and must not be paid by way of offsetting, transfer of benefits in kind or other indirect ways cf. Advertising Order s. 23(2).

Accordingly, healthcare personnel can only receive payment for a service to a pharmaceutical company if the service forms part of a normal, mutually obligating agreement between the person and the company and if the service and consideration are commensurate.

This might for example be payment for renting window space for advertising a medicinal product at a pharmacy, advertising in pharmacy papers, etc. Similarly, it would be possible to pay for doctors' professional assistance in undertaking clinical trials or drawing up information material on medicinal products. With respect to payment for doctors' professional services, it should however be emphasized that commercial relations with a pharmaceutical company do require the prior consent of the Danish Medicines Agency, cf. Pharmacies Act s. 3(2).

5.6. Hospitality and sponsorship, etc.

The prohibition in sec. 5.5 against offering financial inducements to healthcare personal is modified by a series of express exemptions with respect to sponsorship and hospitality, etc.

Advertising Order s. 25(1) states that it is permitted to give or offer healthcare personnel the following financial benefits:

- 1) Hospitality by way of payment on their direct expenses for meals, travelling, accommodation, etc., as part of advertising and professional information on medicinal products, and

2) Trade information and training on medicinal products by way of payment for their direct expenses for training courses, congresses and other professional activities in which healthcare personnel participate or that they hold.

The provisions of s. 25(1.1) give healthcare personnel the option of direct sponsorship for meals, travelling, accommodation, etc. associated with advertising or professional information on medicinal products. This also includes hospitality associated with participation in training courses and other activities for professional medical and pharmacy purposes.

The provisions of s. 25(1.2) give healthcare personnel the option of sponsorship for their direct expenses for internal courses and other professional activities. This might for example relate to fees for external lecturers or expenses for buying training material.

5.6.1. Level and extent

The services noted in Advertising Order s. 25(1.1) must be kept at a reasonable level and be closely restricted to the main purpose of the meeting, including the fact that the time so spent should be minor compared to advertising or professional activities, cf. Advertising Order s. 25(2). This means for example that a professional whole-day seminar from 09-17 hrs could include breakfast on arrival, lunch and possibly a light dinner to conclude the seminar. Services must not include other than healthcare personnel, cf. Advertising Order s. 25(2). Spouses of healthcare personnel can participate in travelling to an event held by a pharmaceutical company provided that the spouses pay all their own costs associated with participation.

5.6.2. Events abroad

Payment may only be made for the services noted in s. 25(1) for advertising or professional activities held abroad if there are significant considerations that so indicate, or for practical or financial reasons, cf. Advertising Order s. 25(3).

This might be because it is considerably cheaper to send a group of healthcare personnel to an event abroad than to organize a comparable event in Denmark.

The significant considerations justifying holding an event abroad must upon request be submitted to the Danish Medicines Agency, cf. Advertising Order s. 25(3).

5.6.3. Public meetings

Pharmaceutical companies are permitted to sponsor meetings held by pharmacies to give clinical information about pharmaceutical products to the general public, cf. Advertising Order s. 26(1).

The amount provided in sponsorship for a pharmacy's clinical information meetings on medicinal products must not exceed the direct expenses for holding the activity concerned, cf. Advertising Order s. 26(2).

If for example pharmacists hold clinical information meetings on their own premises, they cannot receive sponsored fees or hire for the premises. It would on the other hand be lawful for sponsorship to be given for fees for external speakers and the costs of any extra cleaning of premises.

Representatives from the sponsoring company may not actively participate in an event, cf. Advertising Order s. 26(2). If for example pharmacists were to hold clinical information meetings on obesity and a company with obesity products in its range were to sponsor such events, it would accordingly not be permitted for a representative of the company to report on the company's products, treatment of obesity or in some other way contribute to such events.

Similarly, pharmaceutical companies may sponsor public meetings giving clinical information about medicinal products held by the proprietors of stores dealing in non-pharmacy-only OTC products and non-pharmacy-only medicinal products for farm animals when the meetings are about these medicinal products, cf. Advertising Order s. 28.

The prohibition against offering hospitality to the general public as part of advertising and clinical information on medicinal products in Advertising Order s. 20 means that free refreshments cannot be offered at public meetings. Refreshments can only be offered subject to payment.

5.7. Entertainment

Pharmaceutical companies must not pay for participation by healthcare personnel in purely social or cultural events for advertising purposes, cf. Advertising Order s. 27. This prohibition should be interpreted broadly and would cover for example payment for tickets for theatres, museums or football matches. The prohibition applies irrespective of the size of the payment.

The provisions do not, however, include payment of tickets when it comes to professional events in conference facilities, etc. at museums or other cultural locations. Ticket payments are for the purpose of allowing healthcare personnel to participate in a trade event and this is thus not payment for participation in a purely cultural event.

6. Cost-based discounts – delimitation and definition

It follows from Advertising Order s. 21(1) that it is not permitted to give or offer healthcare personnel financial inducements for advertising purposes or otherwise for promoting sales of a medicinal product. A discount would always be a financial inducement for the recipient and accordingly no discounts may be offered to healthcare personnel.

The prohibition does not, however, cover discounts for medicinal products if the discount is based on cost-savings for the supplier as a direct consequence of the procurement patterns exhibited by the recipient that differ from the supplier's standard terms and conditions. Such discounts are called "cost-based discounts", cf. Advertising Order s. 29.

The right to give cost-based discounts covers all medicinal products and covers all retail dealers thereof, including pharmacies.

The regulations for the right to provide cost-based discounts only covers commercial relations between the supplier and retailer regardless of whether the supplier is a pharmaceutical manufacturer, importer or wholesaler. Discounts granted between companies in the distribution chain such as between producer /importer and wholesaler fall outside the regulations for cost-based discounts. Pharmaceutical manufacturers and importers who make their own deliveries to retailers are covered for this part of their business by the full regulations on cost-based discounts.

Cost-based discounts should be calculated on the basis of the supplier's direct, as well as indirect, expenses associated with delivery of pharmaceutical products to pharmacies or to other retailers, such as the costs of administration, payroll, warehousing, and delivery vehicles, etc.

Cost-based discounts may be given, *inter alia*, as a result of agreements for fewer deliveries and larger volumes per order. The supplier gains savings partly because of lower costs for actual delivery and partly because of lower administrative expenses associated with handling deliveries. If a retailer, for example, accepts going from five weekly deliveries to one weekly delivery, this would provide the basis for discounts, provided that the supplier's standard terms of business are five weekly deliveries.

The retailer may be flexible about delivery times. And so a pharmacy with its own stock of medicinal products might accept a certain amount of irregularity with respect to the supplier's delivery dates, enabling the supplier to get the option of organizing the most appropriate and cost-saving (for the supplier) delivery service.

The procurement pattern on which discount payment is based may partly reflect activities by an individual retailer or several dealers together. Accordingly, cost-savings by the supplier on the basis for example on the overall procurement patterns of a number of pharmacies could form the basis for offering discounts.

No discounts could be offered based solely on a change in circumstances at the discount giver (e.g. the wholesaler). As noted above, cost-based discounts predicate an especially rational procurement pattern by a retailer and cannot otherwise be justified by general rationalisation by the discount giver - that might for example result from the wholesaler installing new general cost-saving technology.

There is no requirement in the Order for suppliers to offer discounts. A supplier must however apply the same principles for calculating discounts for recipients demonstrating the same

procurement patterns, Advertising Order s. 29(2). It follows from this that when calculating discounts for recipients with identical procurement patterns, suppliers must apply the same principles when calculating the cost-savings on which a discount is given.. Recipients with the same procurement patterns thus have the same opportunity to get the same discounts for medicinal products with the same handling costs.

It has to be assumed that a discount given under specific terms for the purchase of a specific product number should also be obtainable when purchasing other products numbers supplied on the same basis. It is not possible for the discount to vary from product number to product number for medicinal products with the same handling costs for the same delivery.

A special agreement between a wholesaler and a manufacturer for cost-saving use of warehousing facilities at the wholesaler would not provide justification for special discounts being offered by the wholesaler for the manufacturer's products. On the other hand, differential discounts could be offered for different products where there are special requirements for delivery, such as requirements for special storage conditions. Offering differential discounts for different medicinal products in the same delivery would require the supplier to be able to justify this by special differences in the pharmaceutical products.

Discounts, price reductions and the like in one part of the trade chain would not be regarded as cost-savings with respect to specific deliveries in subsequent links in the chain. Savings on a supplier's purchases of medicinal products from manufacturers would not justify a discount being passed on to retailers. Accordingly, no discounts may be offered that depend on suppliers' purchase prices and margins that can vary between individual manufacturers and products.

Discounts must be commensurate with cost-savings, cf. s. 29(2). The discount may not exceed the cost-savings obtained by the supplier on delivery of medicinal products. The Order does not, however, require suppliers to pass on full cost-savings in discounts.

A discount may only be offered to the direct purchaser of a medicinal product, cf. Advertising Order s. 30(2), i.e. the pharmacies and other retailers whose rational procurement patterns have led to the supplier achieving cost-savings. Discounts may not be passed on to others.

Voluntary associations of pharmacies - pharmacy chains - may negotiate agreements on cost-based discounts on behalf of the pharmacies. The discounts so achieved must however be immediately passed on in their full extent to the pharmacies and must not be accumulated in the chains, cf. Advertising Order s. 36. Pharmacy chains must accordingly not retain a proportion of the discounts and the discounts may not reside in the chains in excess of the period required for administrative purposes, for example associated with bank transfers and issuing invoices or credit notes.

The discount must consist of a reduction in the price of the goods involved in the specific delivery giving rise to a discount, cf. Advertising Order s. 30. It would not be in accordance with the regulations for suppliers to give discounts by way of other financial benefits than by a reduction in the price of the acquisition concerned. Cost-based discounts should be clearly stated on the invoice or the credit note issued immediately after delivery which should state how the discount has been derived and should be separate from other discounts, such as discounts on the OTC products at pharmacies.

6.1. Special rules on mandatory notification, documentation, management statement and audit for discounts on pharmacy-only medicinal products

There are various special supplementary rules that apply to the provision of cost-based discounts on pharmacy-only medicinal products.

The party giving a cost-based discount on pharmacy-only medicinal products must publish information on the entitlement of pharmacies to achieve such discounts, cf. Medicines Act s. 71 b(2) (mandatory notification).

The purpose of mandatory notification is to ensure openness and transparency in the provision of cost-based discounts by suppliers for pharmacy-only medicinal products, so that provision of

discounts is done on a transparent basis. Mandatory notification provides information to pharmacies as to the discounts that are readily available in the marketplace. This provides them with the basis for assessing whether they have obtained the largest discounts possible and whether a discount is such that it is in excess of what is justified by cost-savings.

Openness and transparency in the discount schemes reflect considerations for competitive aspects in the sector. Mandatory notification discloses the supplier's competitive parameters to the general public which may tend to restrict competition. In formulating the regulations for mandatory notification, it has been important to maintain a balance between the openness required in discount schemes and the maintenance of competition in the sector.

The regulations in Advertising Order s. 31 on mandatory notification on cost-based discounts set the framework for notification by suppliers. No detailed regulations exhaustively defining the content of supplier notification are laid down. It is up to individual medical suppliers themselves to define more fully the content of their notification since it is basically the suppliers that are aware of the conditions and costs associated with supplying medicinal products.

The framework that has been set means that notification must be provided for standard terms of delivery that form the basis for standard pricing on which the supplier does not offer discounts. As part of this, information must be given on the standard terms for delivery of pharmacy-only medicinal products. This would typically be details of how often products are delivered, the minimum quantities for a delivery and whether there are requirements for deliveries at special times.

Information and notification must further be given as to the changes in standard terms and conditions that can give rise to discounts. These might amongst other things consist of a reduction in the frequency of delivery, larger quantities /volumes or by being flexible as to delivery times and dates

With respect to the above changes, information must be given as to the size of discount suppliers will provide. Information must be given on the maximum discount obtainable for each type of change as well as the discounts achievable for a combination of several different changes from standard terms. Discounts for the various changes must be stated as a fixed amount or percentage rate or within a range. The range for a given discount does not express an obligation by the supplier to grant the discounts stated in the range to pharmacies.

Information must be published clearly and be easily accessible on the supplier's Internet website, cf. Advertising Order s. 31(1).

It should be noted that pharmacies must not for their part request or receive other discounts than those a supplier is lawfully allowed to grant, cf. Medicines Act s. 71 b(4).

There are special requirements for drawing up and retaining documentation for cost-based discounts provided and received and suppliers' cost-savings on supplying pharmacy-only medicinal products to pharmacies. The discount giver and the pharmacy must retain documentation for discounts received and provided for three years, cf. Advertising Order s. 32 and 33. Documentation by way of invoices, credits notes and other appended material must be made available at the request of the Danish Medicines Agency which can also order a discount giver to demonstrate that a discount has been given in accordance with the regulations, cf. Medicines Act s. 71 b(5-6). Credit notes relating to cost-based discounts must not be issued later than 30 days after delivery has taken place and the deliveries to which a credit note relates must be clearly stated. Medical suppliers must ensure that documentation in accordance with Advertising Order s. 32 is retained so that it is possible to establish a clear trail for deliveries to every individual pharmacy for access to discounts (notification) and invoices /created notes, including details of how the discount has been put together and calculated.

Additionally, medicinal product suppliers must draw up special management statements with respect to the provision of cost-based discounts for pharmacy-only medicinal products. Management statements must state that discounts have been granted in accordance with the information drawn up and published by the supplier on access to cost-based discounts, cf. mandatory notification, and that

discounts have otherwise been provided in accordance with the regulations in the Order, cf. Advertising Order s. 34. Comparable rules on management statements on discounts received apply to pharmacies and chains of pharmacies cf. Order on Financial Reporting by Pharmacies and Pharmacy Chains.

The provision of cost-based discounts on pharmacy-only medicinal products by suppliers is subject to audit by a state-authorized or registered accountant, cf. Advertising Order s. 35. The audit must include testing whether the retained documentation on cost-based discounts satisfies the provisions of the Order. Audit further includes testing whether discounts have been granted in accordance with the information drawn up and published by the supplier on access to cost-based discounts, cf. mandatory notification, and whether cost-based discounts have otherwise been given in accordance with the regulations in the Advertising Order. The precise content of the audit is stated in the audit instructions drawn up by the Ministry of the Interior and Health and the Association of State Authorized Accountants and the Association of Registered Accountants. Comparable rules on management statements on discounts received apply to pharmacies and chains of pharmacies cf. Order on Financial Reporting by Pharmacies and Pharmacy Chains.

6.2. Bonus etc to medicine users

No bonuses or other financial inducements may be offered to users of medicinal products when trading with pharmacy-only medicinal products, cf. Medicines Act s. 71a(1). Users could for example be individuals or associations of medicine users such as a patient association.

There is however a special exemption in that it is permitted for bonuses to be paid to the owner of a hospital in connection with sales of medicinal products to a hospital, cf. Medicines Act s. 71a(2).

7. Homeopathic medicinal products

7.1. Homeopathic medicinal products registered using simplified procedures

The Advertising Order contains some special rules for homeopathic medicinal products registered under a special simplified procedure. The simplified procedure is characterized, *inter alia*, by no documentation being available on the efficacy of the medicinal products.

Neither are there product summaries for the medicinal products. So the ordinary advertising regulations based on product summaries for individual medicinal products cannot be used as they stand.

Advertising Order s. 14 gives the information that must and may be included in advertisements for homeopathic medicinal products for human and veterinary use respectively. Advertisements must not contain other information. However, they may perfectly well contain general advertising statements, pictures, etc.

The provisions of Advertising Order s. 4 on concealed advertising given in s. 10 addresses a series of specific restrictions on the design of advertisements to the general public, and s. 20-30 on financial inducements, hospitality and sponsorship, etc. and discounts apply equally to homeopathic medicinal products as for other medicinal products.

7.2. Other homeopathic medicinal products

The ordinary advertising regulations for medicinal products apply if a homeopathic medicinal product requires approval according to the ordinary rules of the Medicines Act, i.e. by way of a marketing authorization issued by the Danish Medicines Agency or the Commission.

8. Internet

8.1. Advertising on the Internet

Advertising medicinal products on the Internet must comply with the same requirements as advertisements in other media. The regulations must insofar as necessary, however, be read and construed with due deference to the special nature of the Internet, cf. Advertising Order s. 9(1).

The regulations apply to banner advertisements, etc., which are clearly advertising and reference to medicinal products on for example the websites of pharmaceutical companies which must generally be regarded as coming under the concept of advertising, cf. sec. 2 on the concept of advertising.

The advertising regulations distinguish between advertising to the general public and advertising to healthcare personnel. Advertising on the Internet which is generally accessible must comply with the requirements for advertising to the general public.

8.1.1. Advertising to healthcare personnel

The regulations on advertising to healthcare personnel apply to websites which are solely accessible by healthcare personnel and persons engaged in the sale of medicinal products outside pharmacies, cf. Advertising Order s. 9(3).

Access to such websites must be effectively restricted to special groups of persons via a personal access code requirement, etc., cf. Advertising Order s. 9(3). It is not sufficient if the user merely has to enter a password which might in fact be the same for all users. There must at the very least be user identification by way of a unique username, authorization number, etc. and an individual password associated therewith. This might involve a system specially designed for the website concerned or a general system such as the user's digital signature.

8.2. Mandatory information

Medical advertising must include various mandatory information, cf. Advertising Order s. 5 and s. 11. on the Internet where it is possible to use links to connect several websites together. The requirement for provision of mandatory information can be met by an advertisement containing a link to a separate website giving the mandatory information. The actual advertisement must clearly state that the link provides access to additional information.

9. Medical sales representatives

9.1. Definition and training

Medical sales representatives shall be taken to mean people who act on behalf of pharmaceutical companies, etc. to present, inform and advertise medicinal products to healthcare personnel and commercial operators who are entitled to deal in medicinal products.

Medical sales representatives must have undergone suitable training and possess sufficient professional knowledge so that they can give precise, adequate information about the medicinal products they are demonstrating, cf. Advertising Order s. 18(1).

Training may either have been undertaken in the company, at another company or on special training courses, such as the medical representative training course operated by Lif. It is the responsibility of the company to ensure that the representatives they have employed have undergone suitable training and to ensure that they have the requisite clinical knowledge of the company's products.

The work of medical sales representatives is basically bound by the ordinary regulations on advertising medicinal products, including the requirement that an advertisement must be adequate and objective, and not be misleading.

9.2. Provision of product summary etc.

According to Advertising Order s. 18(2), a medical sales representative must provide the person being visited a product summary for each product presented, supplemented with information about prices and reimbursement rules.

The product summary must be provided with the content (including systems and wording) approved by the Danish Medicines Agency although more extensive product information may well be included so long as it is possible to clearly separate the product summary from the other information.

9.3 Reporting side-effects

If medical sales representatives obtain information on the use of the medicinal products being presented from persons said representatives are visiting, including information on side-effects for the medicinal product, this shall be reported by them to the holder of the marketing authorization for the medicinal product. s. 19 Advertising Order.

There are no specific rules on how companies should handle reports from medical sales representatives. Pursuant to Medicines Act s. 53, the holder of the marketing authorization for a medicinal products has, however, an obligation to keep a listing of potential side-effects. Depending on the circumstances, reports from medical sales representatives should be included on this.

10. Provision of medical samples

10.1. Supply to the general public

Medicinal products may not be supplied to the general public without payment. The Danish Medicines Agency can however grant permission therefor if it is not for advertising purposes, cf. Medicines Act s. 67(1). The commentary on the Medicines Act states that the Danish Medicines Agency should be especially cautious about granting free supplies of sample medicines to the general public. It would normally be a precondition that the recipients form a restricted, well delimited group and that the process should be for recognition and not marketing purposes. The provision makes it possible to permit free supplies of medicinal products for example for information purposes.

10.2. Provision to healthcare personnel

The Ministry of the Interior and Health lays down rules on the extent to which medicinal samples may be supplied to healthcare personnel, cf. Medicines M. 67(2). According to s. 1 of the Order on the supply of medicinal products samples, free supplies of medicinal samples may only be provided on the following conditions:

- 1) Medicinal samples may only be supplied to doctors, dentists and veterinarians and only insofar as the person concerned is entitled to prescribe said medicinal products and their use is permitted for the person concerned as part of their medical, dental or veterinary practice.
- 2) Only one sample of each medicinal product may be supplied annually to each doctor, dentist or veterinarian. If the medicinal product is available in several forms or strengths, only one sample of each form and strength may be supplied.
- 3) Medical samples may not be larger than the smallest pack marketed.
- 4) The pack must be marked "Free medical sample - not for resale "
- 5) Medical samples may only be supplied following a written, dated and signed request therefor from the recipient.
- 6) Medical samples may only be supplied by the holder of the marketing authorization or a representative thereof. Samples must not be issued from pharmacies.
- 7) Every medical sample must be accompanied by the product summary relating to the medicinal product.
- 8) Samples of medicinal products covered by the Euphorizing Substances Act must not be supplied.

Holders of marketing authorizations or their representatives shall keep an account of the numbers of samples of individual medicinal products supplied, listed by the form and strength of the product. The accounts, including requests from recipients of samples shall be retained for at least two years and during this period, be accessible to the Danish Medicines Agency, cf. s. 2 Order on the supply of medicinal samples.

Medicinal samples may only be used by a doctor, dentist or veterinarians as part of their practice, cf. Order on the supply of medicinal samples. s. 4.

A medicinal sample must always only be supplied at the written request of a doctor. The request shall include the date and the doctor's signature. The signature of the doctor's secretary is not sufficient.

11. Queries, complaints and recourse

11.1. Queries and complaints

Queries on the rules for advertising medicinal products and complaints about unlawful advertising may be submitted to the Danish Medicines Agency, Axel Heides Gade 1, DK-2300 Copenhagen S, dkma@dkma.dk, cf. however, 11(2).

The advertising complainant can basically not expect anonymity since the complaint is subject to the regulations on the Public Administration Act and the Freedom of Information Act on the right to disclosure for public administration documents.

Decisions by the Danish Medicines Agency's on cases on advertising for medicinal products may be brought before the Ministry of the Interior and Health, Slotsholmsgade 10-12, DK-1264 Copenhagen K.

11.2. TV advertisements

Complaints about medicinal product advertising on radio and TV should be sent to the Radio & TV Board, Media Sekretariat, Vognmagergade 10, 1, DK-1120 Copenhagen K, rtv@mediesekretariat.dk.

The Radio & TV Board will apply to the Danish Medicines Agency for a statement before making a decision on cases of advertising medicinal products.

12. Self-regulation bodies

12.1. Relationship between the Danish Medicines Agency and Self-regulation Bodies

The regulatory function exercised by the Danish Medicines Agency on advertising will be supplemented by the sector self-regulation bodies that monitor the legality of companies' advertising activities alongside the Danish Medicines Agency. There are five self-regulation bodies: The Medical Information Materials Board, VIF's Marketing Board, the Pharmacies Ethics Board, the Medical Ethics Board and the Healthcare Sector Supplier's Ethics Board.

Regardless of whether a complaint about an advertisement falls within the area monitored by the self-regulation boards, a complainant may at any time complain to the Danish Medicines Agency instead. The Danish Medicines Agency may as part of dealing with a complaint, obtain a statement from the relevant self-regulation body.

Decisions made by a self-regulation body cannot as such be appealed to the Danish Medicines Agency. But a dissatisfied party is not precluded from submitting a case to the Danish Medicines Agency even though it has already been dealt with by a self-regulation body. In such case, the decision of the self-regulation body will be included in assessment of the matter by the Danish Medicines Agency

The Danish Medical Association, Danish Pharmaceutical Association, Danish Association of the Pharmaceutical Industry, Danish Generic Medicines Association, Parallel Importers Association made a joint agreement on 13th March 2007 on common rules for collaboration in the medicinal

product area. The parties also signed a letter of intent for the establishment of a new common ethics board – The Board for Self-Regulation in the Medicinal Product Sector (NSL). The Board is to monitor compliance with sector rules on professional collaboration between the pharmaceutical industry and healthcare personnel. The intention is for the new Ethics Board to start work on 1st January 2008, if it has by then been approved by the respective competent general meetings of the parties to the agreement. The new collaboration agreement (self-regulation agreement) became effective on 1st June 2007. The agreement covers all existing agreements between Danish Medical Association, Danish Pharmaceutical Association and the Danish Association of the Pharmaceutical Industry into a single agreement and there has also been an updating process to take into account the latest adjustments to the advertising regulations. In the interim period until the establishment of NSL, compliance with the collaboration agreement will be monitored by the Medical Information Materials Board, the Pharmacies Ethical Board and the Medical Ethics Board.

12.2. Medical Information Materials Board

The Medical Information Materials Board will monitor professional relations between healthcare personnel and the pharmaceutical industry for compliance with current rules, including the provisions of the agreement between the Danish Medical Association and the Danish Pharmaceutical Association. The Board deals with complaints and queries from healthcare personnel and from individuals and companies associated with the Danish Medical Association, Danish Pharmaceutical Association, Danish Association of the Pharmaceutical Industry, Danish Generic Medicines Association and the Parallel Importers Association, complaints from medicinal products suppliers who have acceded to the Board and complaints from other parties who might have a special, acknowledged interest in the matter concerned.

NMI can also instigate proceedings on its own initiative. Finally, NMI can make an initial assessment of medical information material, etc. if a company subject to the Board's authority so requests.

Advertising to the general public comes under the authority of NMI.

Applications should be made to NMI, Strødamvej 50 A, DK-2100 Copenhagen Ø, info@nmidk.dk.

12.3. Veterinary Medicine Association (VIF), Marketing Board

VIF's Marketing Board deals with and makes decisions on complaints about VIF members' advertising activities for veterinary medicinal products.

Applications should be made to VIF, Marketing Board, Strødamvej 50 A, DK-2100 Copenhagen Ø, vif@vif.dk.

12.4. Pharmacies Ethics Board

The Pharmacies Ethics Board monitors that collaboration between the pharmacies and the pharmaceutical industry complies with current regulations, including the provisions contained in the collaboration agreement (self-regulation agreement).

The Pharmacies Ethics Board deals with complaints from pharmacists, suppliers covered by the collaboration agreement, NMI and other parties with a special, acknowledged interest in a particular matter. The Board can also instigate proceedings on its own initiative.

Applications should be made to Pharmacies Ethics Board, Secretariat, Bredgade 54, PO Box 2181, DK-1017 Copenhagen K.

12.5. Medical Ethics Board

The Pharmacies Ethics Board monitors that collaboration between the pharmacies and the pharmaceutical industry complies with current regulations, including the provisions contained in the collaboration agreement (self-regulation agreement).

The Board deals with complaints upon request by medical organizations, members of the Danish Medical Association, NMI and others with a special, acknowledged interest in a particular matter. The Board can also instigate proceedings on its own initiative.

Applications should be made to the Medical Ethics Board, Trondhjemsgade 9, DK-2100 Copenhagen Ø.

12.6. Health Sector Suppliers Association Ethics Board

The Health Sector Suppliers Ethics Board deals with cases on advertising that contravene legislation and the Health Sector Suppliers Association's own ethical rules. The Board can instigate proceedings on its own initiative and the Board and members of the Health Sector Suppliers Association can also request that the Board consider a matter.

The Board can only deal with cases relating to members of the Health Sector Suppliers Association, although it can also make statements in matters of principle regardless of whether these directly relate to members of the Health Sector Suppliers Association.

Application should be made to Health Sector Suppliers Association, Børsen, DK-1217 Copenhagen K, hbl@hts.dk.

13. Previous guidance

Danish Medicines Agency's Guidance No. 166 of 5th October 1998 on advertising for medicinal products has been revoked.

Danish Medicines Agency, 24th May 2007

Elin Andersen

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13. Previous guidance

Official notes

¹⁾ As amended by Order No. 393 of 27 April 2007

²⁾ "data on file" shall be taken to mean a final, signed study report reviewing the results of the study derived from statistically processing data in accordance with the protocol. Detailed results, including individual data, shall be given in one or more appendices. The design, treatment, patient documentation and the most important results are given in a summary, exhaustive synopsis of the report. The reference gives the report's full title and study code, the name of the principal investigator and the medical officer in charge and the year and company name.