Guideline on Advertising, etc. of Medicinal Products[1]

1. Advertising rules

The rules on advertising of medicinal products are found in Part VII (sections 63-70) of the Danish Medicines Act, Executive Order no. 1153 of 22 October 2014 on Advertising, etc. of Medicinal Products (the Advertising Order) and Executive Order no. 1244 of 12 December 2005 on the Supply of Medicinal Product Samples.

Furthermore, the Advertising Order lays down rules on medicinal product discounts, and sections 71A-71C of the Danish Medicines Act and section 3B of the Danish Pharmacy Act lay down rules on bonuses and discounts offered in connection with the sale of pharmacy-only medicinal products. These rules are also mentioned in this guideline.

2. Definition of advertising and scope of rules

2.1. Definition and scope

The term advertising in the context of the pharmaceutical legislation is defined in section 1(1) of the Advertising Order: Advertising of medicinal products means any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products.

The definition of advertising of medicinal products is interpreted in a broad manner pursuant to the wording of the provision and the main purposes of the advertising rules, which are to protect human and animal health.

The rules cover any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products.

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

In Case C-421/07, the European Court of Justice has stated that the definition of medicinal products in article 86(1) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, is to be interpreted as meaning that dissemination by a third party of information about a medicinal product, including its therapeutic or prophylactic properties, may be regarded as advertising within the meaning of that article, even though the third party in question is acting on his own initiative and completely independently, de jure and de facto, of the manufacturer and the seller of such a medicinal product if the dissemination by a third party specifically constitutes a form of door-to-door information,

[1] Guideline no. 10356 of 29 December 2014 (Guideline on Advertising of Medicinal Products)

canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products.

It is determined on a case-by-case basis whether the dissemination by a third party of information about a medicinal product constitutes a form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products. The Advertising Order's definition of advertising of medicinal products implements article 86(1) of the Directive.

The advertising rules apply to all types of medicinal products for human beings and animals, including herbal medicinal products, traditional herbal medicinal products, homeopathic medicinal products and strong vitamins and minerals with the few modifications following from the Danish Medicines Act and the Advertising Order.

2.2. Exemptions

Pursuant to section 2 of the Advertising Order, the rules on medicines advertising do not apply to:

1) The labelling and package leaflet of the medicinal product, cf. the Executive Order on Labelling etc. of Medicinal Products.

2) Correspondence of an individual nature, if required accompanied by documents of a non-promotional nature, intended to answer a specific question about a certain medicinal product.

3) Necessary and specific information or documentation which serves safety purposes and not promotional purposes, e.g. information about changes to the packaging, new adverse reactions or manufacturing defects. The meaning of safety purposes is broad, implying that e.g. information on how to open a medicine package without damaging the medicinal product is also considered serving a safety purpose in the meaning conferred by the Advertising Order.

4) Price lists, product catalogues, etc. containing no other information about the medicinal products than their names, pharmaceutical forms, strengths, pack sizes, prices and images of the product packaging, including price lists, product catalogues, etc. that are published on the internet for the purpose of selling the medicines online.

5) Informative material on health and disease provided that no reference, neither direct nor indirect, is made to specific medicinal products. This could be anything from conventional leaflets to comprehensive internet websites.

6) Patient information folders handed out by either a prescriber when prescribing a medicinal product or a pharmacy when dispensing a medicinal product, provided the folder contains only factual information of significance to the patient and relatives. The information in the folder must not be inconsistent with the summary of product characteristics (SPC). The patient information folder given to the patient can be in print and electronic form. Patient information folders will be considered as advertising if containing claims, information, images, illustrations, or the like that, wholly or mainly, serve promotional purposes. For instance, a patient information folder would be considered as advertising if containing subjective claims about the medicinal product. This would include claims stating that a medicinal product is fast-acting, effective, easy to handle, the best of its kind, the most preferred medicine, is easier to administrate than competing brands or is

one of the safest medicines available. As mentioned, the patient information folder must only contain factual information of significance to the patient or relatives. The patient information folder should equally describe the medicine's effect and adverse reactions/risks.

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

8) Unedited and unabbreviated reproduction of a package leaflet, the approved summary of product characteristics (SPC), a publicly available assessment report, cf. section 72(1) of the Danish Medicines Act, or a picture of a medicinal product package, provided the information is made available in a manner implying that the users will need to search for the information actively. This means that a company could place, for example, a list with the names of its medicinal products on its website with a link to the SPCs and package leaflets for each product.

Informative material on medicinal products prepared by public medicines committees or other public institutions with the purpose of promoting rational use of medicines is not subject to the rules on medicines advertising.

It is not considered to be advertising when a company responds to an enquiry by a health professional by sending a scientific article about a clinical trial to that health professional, as long as the article is forwarded without comments or supplementary material. The article must in advance have been published in an accredited and independent Danish or foreign professional journal, or similar. This applies equally to uncommented scientific articles that contain results from comparative studies of different medicinal products.

2.3. Health professionals and the public

The advertising rules distinguish between advertising to the public and advertising to health professionals. Health professionals mean doctors, dentists, veterinarians, pharmacists, nurses, veterinary nurses, pharmaconomists, midwives, bioanalysts, clinical dietitians, radiographers, social and healthcare assistants or students within these fields, cf. section 1(3) of the Advertising Order.

Anyone who is not a health professional is considered the public, cf. section 66(2) of the Danish Medicines Act and section 1(2) of the Advertising Order. However, there are a few exceptions as regards persons who handle medicinal products as part of their profession although they are no health professionals. This group covers owners and managerial staff of shops authorised to sell non-pharmacy medicinal products or medicinal products for production animals, and persons who as part of their profession offer advice on and purchase medicinal products

in a non-pharmacy context, including persons in the hospital sector, cf. Part VIII of the Advertising Order. Further details are provided in sections 4.6 and.4.7.

3. General provisions

3.1. General advertising requirements

Section 63 of the Danish Medicines Act lays down the general requirements for the content and form of medicinal product advertisements. The provision applies to both advertising to the public and advertising to health professionals.

Firstly, advertising must be adequate. For instance, an advertisement must contain adequate information so that recipients can understand and assess when and under which circumstances the medicine can and should be used and when not to use it.

By contrast, an advertisement is not adequate if it uses such broad terms that it is likely to promote the consumption of a medicine when in fact it is not particularly suitable to use under the given circumstances.

The provisions detailing that an advertisement must contain a number of compulsory details, see sections 4.4 and 5.1 below, are based on the requirement for medicines advertising to be adequate.

Secondly, advertising must be factual. Therefore, medicinal products must not be marketed in the same aggressive and consumption-encouraging manner as general consumer goods. Advertisements for medicinal products must not be designed to or likely to generate unnecessary increases in the consumption of medicines. The advertisement must furthermore be based on professional and relevant information about the medicinal product. Whether an advertisement fails to be factual is determined by assessing the form and content in each specific case.

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

- Gifts offered in connection with advertising of medicinal products to the public.
- Competitions and prizes linked to the promotion of medicinal products to the public.
- Advertising of medicinal products containing offers that highlight great discounts and heavily reduced prices such as "buy now" offers that otherwise contain only little information about the medicinal products.

In regard to healthcare professionals, reference is made to the Advertising Order’s section 22(2) on gifts, and section 23 on the prohibition against competitions and prizes, see section 5.6 below.

Thirdly, advertising must not mislead or exaggerate the properties of a medicinal product. This means that the form and content of an advertisement must not lead medicine users and persons prescribing or dispensing medicinal products to form misconceptions about the medicinal product, including its effects, adverse reactions, price, ingredients, etc. disease or treatment. Nor must an advertisement put a medicinal product in a more favourable position than other corresponding and perhaps even more suitable medicinal products.

An advertisement for a medicinal product must neither in form nor content mislead or be designed to mislead the persons it is aimed at.

Fourthly, the information contained in the advertisement must comply with the approved summary of product characteristics (SPC). The particulars in the SPC include information about the composition of the product, pharmaceutical form, therapeutic indications (applications), contraindications, adverse reactions, precautions for use, dosage and warnings, if any.

This means that the factual content of the advertisement must not be inconsistent with the particulars of the SPC. It is possible to deviate from the wordings of the SPC to the extent that the requirement for factual information is met. An advertisement may include statements that supplement the information in the SPC, provided they confirm or specify information in the SPC and the information otherwise complies with the SPC. The information in the advertisement must not be misleading or exaggerate the properties of the medicinal product. An advertisement for a medicine must only include information about authorised indications as appearing from the authorised SPC.

3.2. Comparative advertising

If an advertisement includes a comparison of several medicinal products, it must be clear which medicinal products are being compared. Comparisons are only allowed for medicinal products whose comparisons are relevant from an objective point of view, i.e. medicinal products that share the same indication(s), cf. section 16(1) of the Advertising Order.

An advertisement that compares prices is only adequate if it includes information about the current prices subject to the price comparison, cf. section 63 of the Danish Medicines Act.

A comparison is basically only adequate, cf. section 63 of the Danish Medicines Act, when it covers all generic (and any parallel imported) medicinal products that neither differ in therapeutic form nor strength or differ substantially in pack size. Medicinal products with an insignificant market share can be excluded from the comparison. A market share of up to 2-3 % is generally considered as insignificant.

Section 16(2) of the Advertising Order provides that comparative advertising must be prepared on the basis of the information appearing from the SPCs of the products being compared – in so far as the SPC includes information about the particulars being compared. If a comparison concerns prices of pharmacy-only medicinal products, the comparison can be made on the basis of the prices published on medicin.dk.

Since it is prohibited in section 10(1)(iii) of the Advertising Order to give the public the impression that the effect of a medicinal product is better than or equivalent to the effect of another medicinal product, advertisements directed at the public must not compare the effects of several medicinal products, cf. section 16(3) of the Advertising Order.

3.3. Medicinal products not sold in Denmark

Section 64(i) of the Danish Medicines Act prohibits any advertising of medicinal products which are not sold or dispensed legitimately in Denmark.

A new medicinal product can first be sold legitimately from the time it has been approved by means of a marketing authorisation. Additionally, anyone placing a pharmacy-only medicinal product on the Danish market must notify its price to the Danish Health and Medicines Authority no later than 14 days prior to the price's effective date, cf. section 77(1) of the Danish Medicines Act. For some non-pharmacy medicinal products it is required that their available pack sizes have been notified to the Danish Health and Medicines Authority, also at 14 days' notice, cf. section 78(1) of the Danish Medicines Act.

3.4. Magistral medicinal products

Section 64(ii) of the Danish Medicines Act prohibits the advertising of medicinal products prepared in accordance with a magistral formula (magistral medicinal products). This prohibition follows naturally from the fact that magistral medicinal products are prepared for an individual person or animal on directions from a doctor or veterinarian.

3.5. Special medicinal products

Section 3(iii)-(v) of the Advertising Order prohibits the advertising of

- medicinal products for non-clinical trials and clinical trials when a marketing authorisation has not been issued for the medicinal products,
- medicinal products sold of dispensed according to a special compassionate use permit according to section 29 of the Danish Medicines act, and
- sera, vaccines, specific immune globulins and other immunological investigational products not covered by a marketing authorisation, and which are sold or supplied by the SSI (Statens Serum Institut) or the National Veterinary Institute, Technical University of Denmark, in accordance with section 30 of the Danish Medicines Act.

3.6. Storing of advertisements

Pursuant to section 68(1) and (2) of the Danish Medicines Act, the holder of a marketing authorisation for a medicinal product must keep a copy of or other documentation of any form of advertising for a medicinal product for at least two years. In this period, the marketing authorisation holder must keep a copy of all advertising material regardless of form. The material must be made available to the Danish Health and Medicines Authority on request.

According to section 17(2) of the Advertising Order, the advertising material must be stored in print or similar form, or electronically in a generally available format. In other words, a print advertisement can be stored either in paper form or similar hardcopy or electronically. Even though an advertisement has been printed in various journals, hung as a poster or handed out as a folder or other formats, there is no requirement for storing a paper version.

A generally available electronic format means formats (file types) that are commonly used in Denmark and which normally do not cause problems, neither when displaying the file content on a computer nor when exchanging the files between various parties. The file types include the presentation format PDF (Portable Document Format;

suffix: . pdf) as well as the image formats TIFF (Tagged Image File Format; suffix: tif or . tiff) and JPEG (Joint Photographics Expert Group; suffix: . jpeg or . jpg).

In addition to the advertisement itself, the person advertising for a medicinal product must keep information about how the advertisement was used in practice, cf. section 17(3) of the Advertising Order:

1) The advertisement's target audience, i.e. the group that the advertisement was directed at.
2) Distribution method.
3) A list of media in which the advertisement was placed.
4) The period when the advertisement was running.

If someone else than the marketing authorisation holder is advertising for a medicinal product, the obligation to store the advertisement rests on that other someone who thus becomes responsible for the advertisement, cf. section 68(3) of the Danish Medicines Act. This would include retail distributors or parallel distributors, etc.

Pursuant to section 68(4) of the Danish Medicines Act, the Danish Health and Medicines Authority may request to receive any required information from the party responsible for the advertisement in order to check that the advertisement is legitimate.

The provision gives e.g. the Danish Health and Medicines Authority the possibility to request detailed information about the expenses incurred by a pharmaceutical company at a trade congress to check if any participants have received gifts or other economic advantages unlawfully, cf. Part VII of the Advertising Order.

3.7. Orders

By virtue of section 69 of the Danish Medicines Act, the Danish Health and Medicines Authority may order that any unlawful advertising of a medicinal product be withdrawn.

The Danish Health and Medicines Authority may furthermore order the party responsible for an unlawful advertisement to publish a decision stating that the advertisement is withdrawn or to publish a new corrected advertisement. The Danish Health and Medicines Authority may decide the form and content of such publication, including where it should be issued.

3.8. Use of the word pharmacy

It follows from section 65 of the Danish Medicines Act that the word “pharmacy” must not be used in advertisements for non-pharmacy medicinal products, cf. section 60(1), 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.

Thus, the word »pharmacy« must generally not be used in advertisements for non-pharmacy medicinal products, cf. section 65 of the Danish Medicines Act, i.e. certain over-the-counter (OTC) medicinal products, herbal medicinal products, strong vitamins and minerals as well as a number of veterinary medicines, etc.

However, if the party responsible for an advertisement can prove that the medicinal product is sold in more than half of the pharmacies in Denmark, using the word »pharmacy« is allowed. The requirement for the medicinal product to be sold in the majority of pharmacies must be satisfied at all times and provable to the Danish Health

and Medicines Authority. The requirement for proof would generally be considered satisfied if an independent wholesaler confirms that the medicinal product is sold routinely to a majority of pharmacies.

Pharmacies have an obligation to sell all pharmacy-only medicinal products, and therefore it is always permitted to use the word »pharmacy« in advertisements for such medicinal products.

4. Advertising to the public

4.1. Prescription-only medicinal products, etc.

Section 66(1) of the Danish Medicines Act prohibits advertising to the public of the following products:

1) Prescription-only medicinal products.

2) Medicinal products that are inappropriate to use without the patient having first consulted a doctor for diagnosis of the disease or monitoring of the treatment, i.e. medicines which cannot or should not reasonably be used without prior advice from a doctor.

3) Medicinal products covered by the Danish Act on Euphoriant Substances. Due to the provision of item 1 above, this provision is limited to a very small independent area.

The public means anyone who is not a doctor, dentist, veterinarian, pharmacist, nurse, veterinary nurse, pharmaconomist, midwife, bioanalyst, clinical dietitian, radiographer, social and healthcare assistant or a student within one of these fields, cf. section 66(2) of the Danish Medicines Act.

4.2. Professional journals

It is legal to advertise for prescription-only medicines in professional journals directed at health professionals since advertisements in such media are not considered advertising to the public, even if these journals may inevitably be read by others than health professionals. A journal is considered to be a professional journal if its content is predominantly of a professional nature and the vast majority of its readers and subscribers are health professionals.

Pursuant to section 66(3) of the Danish Medicines Act, the Danish Health and Medicines Authority may permit professional journals whose audience is not health professionals to advertise for pharmacy-only medicinal products, in which case the journal in question must submit a reasoned application to the Danish Health and Medicines Authority. In deciding whether to grant permission, the Danish Health and Medicines Authority attaches importance to whether the professional group has a specific and creditable interest in the use of and knowledge about prescription-only medicinal products. The permission may, depending on the circumstances, be limited to certain types of medicinal products.

4.3. Surreptitious advertising

Advertising directed at the public should be presented in such manner that it is clear that it is advertising and that the product being advertised is a medicinal product, cf. section 4 of the Advertising Order. This is to ensure that the target group knows that the information conveyed is an advertising message and may assess the message in that view.

Any form of surreptitious advertising of a medicinal product is, in other words, prohibited, e.g. advertising camouflaged as editorial text in a journal, exposure of a medicinal product in a film (so-called »product placement«) or games on the internet with an underlying advertising message.

4.4. Compulsory information

Pursuant to section 5(1) of the Advertising Order, an advertisement for a medicinal product must contain the below-listed information (compulsory information), see, however, sections 4.4.1-3 below regarding special requirements for compulsory information in advertisements outdoor, in film, radio and TV, etc.:

1) The name of the medicine and the common name.

The common name is determined unambiguously in connection with the authorisation of the medicinal product. The common name must clearly indicate the contents of the medicinal product. This condition is not fulfilled if, e.g. the common name is solely mentioned in a warning against misuse of the active substance in question.

2) Pack sizes.

All available pack sizes must be indicated, see, however, section 4.4.4 regarding veterinary medicines.

3) A reference to the current price on medicinpriser.dk if it is a pharmacy-only medicinal product, cf. section 60(1) of the Danish Medicines Act. If an advertisement for a medicinal product gives information about the product's price, the price indicated must as far as possible be current, i.e. ruling at the time the advertisement reaches the recipient, cf. section 63 of the Danish Medicines Act. An advertisement that compares prices is only adequate if it includes information about the current prices subject to the price comparison, cf. section 63 of the Danish Medicines Act.

4) Effect (authorised indications)

The effects of the medicinal product must comply with the summary of product characteristics (SPC). If the wording of the SPC is considered difficult to understand for ordinary medicine users, it may and should be rewritten into readily understandable terms. It is possible to omit therapeutic indications which the marketing authorisation holder considers irrelevant to ordinary medicine users (or special groups of medicine users which the advertisement is specifically directed at).

5) Adverse Reactions.

The adverse reactions appearing from the SPC must generally be included in the compulsory information. It is possible, however, to omit adverse reactions that are assessed less relevant because of rarity, nature or other objective criteria. This assessment should be made by no other than the marketing authorisation holder and not by others (e.g. a chain of stores) who prepare their own advertisements for a medicinal product. If requested by the Danish Health and Medicines Authority, the marketing authorisation holder must explain why adverse reactions in the SPC have been omitted.

5) If a medicinal product has no adverse reactions, the mention of adverse reactions can be omitted. It is not allowed to indicate statements such as »Adverse reactions: None«, or ”No adverse reactions” cf. section 10(1)(iii) of the Advertising Order.

6) Dosage.

The dosage must be specified in compliance with the SPC. However, dosages used in therapeutic indications that have been omitted, cf. the above, are not to be included.

7) An express invitation to the user to read the information in the package leaflet or on the package.

8) Other information necessary for the correct and appropriate use of the medicinal product, e.g warnings or drug interactions.

It is at the discretion of the marketing authorisation holder to determine which particulars are necessary to include to enable consumers to form a correct and adequate picture of the medicinal product and its use, cf. section 63 of the Danish Medicines Act. In general, any contraindications, special precautions for use, drug interactions, relevant overdose risks, withdrawal periods and special warnings that are mentioned in the SPC should be included in the advertisement. Information which, based on objective criteria, is considered irrelevant to give to the public can be omitted. If requested by the Danish Health and Medicines Authority, the marketing authorisation holder must explain why one or more particulars from the SPC have been omitted.

4.4.1. Advertisements outdoor, on film and in radio

Pursuant to section 6 of the Advertising Order, advertisements appearing outdoor, in film, including video film, and on the radio must include the following information:

1) The name of the medicine and the common name. If a medicinal product contains more than one active substance, the common name may be omitted.

2) Effect.

3) Important adverse reactions.

4) An express invitation to the user to read the information in the package leaflet or on the package.

5) An express invitation to contact a doctor (or veterinarian) or pharmacy in case of doubt.

4.4.2. Advertising on TV

Pursuant to section 7(1) of the Advertising Order, advertising on TV must include the following information:

1) The name of the medicine.

2) Effect.

3) Important adverse reactions.

4) An express invitation to the user to read the information in the package leaflet or on the package.

5) An express invitation to read more about the medicinal product on the concerned TV channel's teletext pages and on the internet. The marketing authorisation holder must publish all information mentioned in section 5 of the Advertising Order on the teletext pages and the internet.

6) The teletext page number and internet address where the information under item 5 has been provided.

The information must either be easy to read on screen or read aloud. The teletext page number and internet address must, however, be displayed on the screen, cf. section 7(3) of the Advertising Order.

4.4.3. Advertising on shop monitors

The rules applicable to advertising on TV also apply to advertising on monitors (screens) in pharmacies or other shops that sell medicinal products provided that there is free access to the internet from a computer, information stand or other means in the pharmacy or shop, cf. section 7(4) of the Advertising Order.

The advertisement must explicitly mention such free access to the internet in the pharmacy or shop and must refer to the internet address where further information can be found about the medicinal product.

All information must be displayed as text on the screen, cf. section 7(5) of the Advertising Order. Contrary to advertising on TV, it is not sufficient that the compulsory information is read aloud.

The rules on advertising of homeopathic medicinal products on monitors (displays) in pharmacies or other shops selling homeopathic medicinal products are provided in section 14(5) of the Advertising Order.

4.4.4. Veterinary medicines

If a veterinary medicine product has been authorised for use in several species, the compulsory information must generally include information about the product’s application in each species.

If an advertisement is intended only to be directed at persons with a specific interest in a single species only, the compulsory text may be limited to information relevant to that particular species, cf. to section 5(3) of the Advertising Order.

To illustrate, the compulsory text of an advertisement for a medicine authorised for use in calves, cows, pigs, poultry, dogs and cats may in a journal for pig farmers be limited to information about the product's use in pigs, and may in a brochure handed out at a pharmacy that which is exclusively about the treatment of dogs be limited to information about the medicine's use in dogs.

If the compulsory text in this way is targeting a specific species, any information that is irrelevant to the treatment of that species must be omitted.

A brochure which describes the general effect of a medicinal product and is handed out to a multitude of persons must include the compulsory text in full, i.e. information about the product’s indications in all species.

4.4.5. Requirements to form, etc.

All compulsory information must appear (or be read aloud) in a manner so clearly that the advertisement's natural target group has no trouble reading or hearing it to grasp the information, cf. section 8 of the Advertising Order.

When the compulsory information is presented as text, which is the norm, the letter height and thickness as well as the contrast between text and background must be adjusted to the circumstances in which the target audience sees the advertisement, taking into account factors such as viewing distance and lighting conditions.

If an advertisement like a display window consists of several elements forming a coherent whole, the compulsory information need not necessarily appear from each element. It is sufficient that the compulsory information appears from one single, separate element that is part of the display on equal terms as the other elements.

4.5. Specific prohibitions

Section 10(1) of the Advertising Order sets out a number of specific restrictions as to the content of advertisements to the public. An advertisement must not

1) give the impression that it is unnecessary to consult a doctor or veterinarian,

2) give the impression that a surgical operation is unnecessary,

3) give the impression that the effects of taking the medicinal product are guaranteed, are without adverse reactions or are better than or equivalent to the effect of another treatment, including a medicinal product,

4) give the impression that the general health can be enhanced by taking the medicine,

5) give the impression that the health could deteriorate by not taking the medicinal product,

6) be directed exclusively or principally at children,

7) include recommendations by health professionals, scientists or other persons, associations of persons, institutions, companies, etc. who/which, by virtue of their prestige, etc. could encourage the consumption of medicinal products, see 4.5.1 below,

8) compare the medicinal product with a foodstuff, cosmetic or other consumer product,

9) give the impression that the safety or efficacy of the medicinal product is due to the fact that its active substances are natural,

10) be such that it might lead to erroneous self-diagnosis,

11) contain exaggerated, alarming or misleading claims of recovery,

12) use, in exaggerated, alarming or misleading terms, visual representations (pictures, illustrations, etc.) of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.

4.5.1. Recommendations by persons of particular prestige

The prohibition against using persons, etc. of particular prestige, etc., cf. section 10(1)(vii), extends to persons whose prestige is conferred by their educational background, work or similar, and persons whose prestige comes from personal qualities.

Firstly, the term “prestige, etc.” covers the prestige or respect that persons and associations of persons have because of their specialist knowledge or expertise, e.g. health persons, scientists or professors.

Secondly, the term "prestige, etc." covers celebrity which is related neither to medicinal products, health and so forth nor a particular status associated with a specific profession. This could be either public persons such as actors, sports celebrities, and TV hosts, or anonymous persons who hold positions that confer particular prestige or authorisation, e.g. police officers.

The prohibition covers not only individuals, but also associations of persons, institutions, companies and the like. Therefore, just like a doctor or a famous football player must not advertise for medicinal products, the same goes for hospitals, medical associations or entire football teams.

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

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

4.6. Advertising to personnel, etc. in certain shops

Advertising to owners of or managerial staff in shops authorised to sell non-pharmacy OTC medicinal products or medicinal products for production animals is covered by the same provisions on compulsory information, reminders and information material which apply to health professionals when the advertisement concerns such medicinal products, cf. section 34 of the Advertising Order. See sections 5.1-4 below for further information about these provisions.

Owners of or managerial staff in shops authorised to sell non-pharmacy OTC medicinal products or medicinal products for production animals are also governed by the provisions on economic advantages, etc. in sections 22-30, section 36 and section 37. However, the provisions apply only if the economic advantage concerns such medicinal products, cf. section 34 of the Advertising Order.

Therefore, this group of persons shall be equated with health professionals in regard to the rules on economic advantages, etc. in Part VII of the Advertising Order. This implies, among other things, that in connection with advertising of or professional information about such medicinal products, hospitality may be provided or offered in the form of payment of direct expenses for meals, travel, accommodation, etc. to persons covered by section 34. See sections 5.6-5.9 and 6 for further information about the provisions on economic advantages, etc.

In addition, owners of shops authorised to sell non-pharmacy medicinal products or medicinal products for production animals are prohibited from giving or offering hospitality to the public in connection with advertising of medicinal products, cf. section 20 of the Advertising Order.

4.7. Advertising to persons who on a professional basis give advice about and purchase medicinal products

Advertising to persons who on a professional basis give advice about and purchase medicinal products in a non-pharmacy context, including persons in the hospital sector, is covered by the same provisions on compulsory information, reminders and information material which apply to health professionals, cf. section 35 of the Advertising Order. See sections 5.1-4 below for further information about these provisions.

The rules on economic advantages, etc. in sections 22-30 apply also to persons who on a professional basis give advice about and purchase medicines in a non-pharmacy context, including persons in the hospital sector, cf. section 35 of the Advertising Order.

Persons who on a professional basis give advice about medicinal products mean persons who on a professional basis offer professional advice about medicinal products to municipalities, regions, the government, hospitals and

other healthcare institutions. This could be advisers and other persons who offer professional advice about medicinal products as part of their profession. The provision does not cover pharmacy staff or medical sales representatives employed by a pharmaceutical company. Persons who purchase medicinal products mean persons who are employed to purchase medicinal products, i.e. purchasing agents employed at hospitals, in regions, municipalities or self-governing institutions. The provision does not cover pharmacy purchasing agents.

The group of persons covered by section 35 of the Advertising Order shall therefore be equated with health professionals in regard to the rules on economic advantages, etc. in Part VII of the Advertising Order. This implies, among other things, that in connection with advertising of or professional information about such medicinal products, hospitality may be provided or offered in the form of payment of direct expenses for meals, travel, accommodation, etc. to persons covered by section 35. See sections 5.6-5.9 for further information about the provisions on economic advantages, etc.

4.8. Hospitality

In connection with advertising of medicinal products, hospitality in the form of payment of expenses for meals, travel, accommodation, etc. must not be offered or given to the public, cf. section 20 of the Advertising Order. The prohibition is absolute, regardless of extent and value of hospitality.

5. Advertising to health professionals

5.1. Compulsory information

Pursuant to section 11(1) of the Advertising Order, advertising directed at health professionals must include the information in items 1-11 (compulsory information):

1) The name of the medicine and the common name. Combination products without a common name must carry clear information about all common names for all active substances.

2) The name of the marketing authorisation holder.

3) Therapeutic indications as specified in the summary of product characteristics (SPC). If an advertisement is exclusively directed at a defined group of health professionals, the indication text may be abbreviated to include only the indications relevant to that group.

Generally, the wordings of the SPC should be included verbatim in the compulsory information. If the indication text in the SPC is so extensive that it would be inappropriate to include it verbatim, it may be rewritten and abbreviated, e.g. leaving out less relevant information.

Under no circumstances may the indication text be rewritten in a way that could lead to misunderstandings, including suggesting that therapeutic indications are different or more extensive than indicated in the SPC.

If the wording of the SPC is not reproduced verbatim, this must clearly appear from the advertisement. Furthermore, it must appear clearly that the full SPC can be obtained from the marketing authorisation holder. The following phrase can be used:

»The indication text has been rewritten and/or abbreviated compared to the authorised summary of product characteristics. The summary of product characteristics can be ordered free of charge from xx (the marketing

authorisation holder)«. This information must be written in a font size which is larger than or otherwise clearly distinctive from the format of the compulsory text. If the information is missing, the advertisement is inadequate and consequently non-compliant with section 63 of the Danish Medicines Act.

4) Contraindications.

Generally, any contraindications contained in the SPC must be included in the compulsory text. If the contraindications in the SPC are so extensive in length or terminology that it would be inappropriate to reproduce them verbatim, the text may be rewritten and abbreviated, e.g. leaving out less relevant information.

Precisely which contraindications to include is based on an estimate. Such estimate must be based on objective criteria with due regard to the requirements of section 63 of the Danish Medicines Act.

If contraindications from the SPC are omitted or rewritten, this must appear clearly from the advertisement. Furthermore, it must appear clearly that the full SPC can be obtained from the marketing authorisation holder. Reference is made to the proposed phrase under therapeutic indications above.

5) Adverse reactions and risks.

Generally, any adverse reactions and risks, i.e. interactions, warnings, overdose risks, withdrawal periods, etc. contained in the SPC must be included in the compulsory text. If the wordings of the SPC are so extensive in length or terminology that it would be inappropriate to reproduce them verbatim, the information can be rewritten and abbreviated, leaving out information considered less relevant in the specific case.

If the wordings of the SPC are not used, it must appear clearly from the advertisement. Furthermore, it must appear clearly that the full SPC can be obtained from the marketing authorisation holder. Reference is made to the proposed phrase listed under therapeutic indications above.

6) Dosage.

The dosage must be specified in compliance with the SPC. If the wordings of the SPC are so extensive in length or terminology that it would be inappropriate to reproduce them verbatim, the dosage information can be rewritten and abbreviated, leaving out information considered less relevant in the specific case.

If the wording of the SPC is not used, it must appear clearly from the advertisement. Furthermore, it must appear clearly that the full SPC can be obtained from the marketing authorisation holder. Reference is made to the proposed phrase under therapeutic indications above.

The rewriting of dosage information should be done very carefully as changed wordings must not lead to misunderstandings.

7) Pharmaceutical forms.

Generally, all pharmaceutical forms available must be specified. If a medicinal product is authorised in several pharmaceutical forms with different indications, and the advertisement is only about one of the pharmaceutical forms, the advertisement must include information about that pharmaceutical form only. Furthermore, it must appear from the advertisement that the medicinal product is also available in other pharmaceutical forms, cf. section 11(2) of the Advertising Order.

For information about medicinal products used in several species, see 5.2 below.

8) Pack sizes.

All of the medicinal product's available pack sizes must be indicated. In special cases where only some of the indications are included in the advertisement, cf. above, any pack sizes that are irrelevant to the concerned indications should be omitted. Also see 5.2 below about medicinal products for several species.

9) Reference to the current price on medicinpriser.dk if it is a pharmacy-only medicinal product. If an advertisement for a medicinal product gives information about the product's price, the price indicated must as far as possible be current, i.e. ruling at the time the advertisement reaches the recipient, cf. section 63 of the Danish Medicines Act. An advertisement that compares prices is only adequate if it contains information about the current prices subject to the price comparison, cf. section 63 of the Danish Medicines Act.

10) Dispensing group.

11) Reimbursement status.

Whereas the advertisement must include information about any general reimbursement available for the medicinal product, it should not include information about the possibilities of obtaining special individual reimbursement. If, in exceptional cases, there is reason to include information about individual reimbursement, e.g. single reimbursement, the advertisement must explicitly state that any reimbursement is individual and granted upon application only.

All compulsory information must appear in a manner so clearly that the advertisement's natural target group has no trouble reading it, cf. section 11(4) of the Advertising Order.

5.2. Veterinary medicines

If a veterinary medicine is authorised for use in several species, the compulsory information must generally contain information about the product's use in each species. If the advertisement only mentions treatment of one single species, the compulsory text may be limited to information relevant to that particular species, cf. section 11(3) of the Advertising Order.

If this is the case, the compulsory text must generally be adjusted to fit the species in question, i.e. leaving out information about irrelevant pharmaceutical forms or pack sizes, etc.

If the compulsory text has been abbreviated to mention treatment of only one species, it must clearly appear that the medicinal product is also authorised for treatment in other species. Furthermore, it must appear that information about all species can be found in the SPC, which can be obtained from the marketing authorisation holder. Failure to do so renders the advertisement inadequate, cf. section 63 of the Danish Medicines Act.

5.3. Reminders (promotional aids)

Advertisements that are directed only at health professionals may be limited solely to the name and common name of the medicinal product, cf. section 12 of the Advertising Order. If other information is included, e.g. indications or prices, the advertisement falls outside the scope of this provision, which means all compulsory information must be included. Company name and logo that identify the sender of the advertisement can be included, however.

5.4. Information material

Pursuant to section 13 of the Advertising Order, any information material about a medicinal product which is distributed or given to health professionals for promotional purposes must include at least the information specified in section 11(1) of the Advertising Order (the compulsory information, cf. above) as well as the date when the material was prepared or last updated.

All information in the material must be accurate, current, verifiable and adequately detailed, enabling the recipient to form his own personal opinion about the medicine's therapeutic value, cf. section 13(2) of the Advertising Order. Any quotations, tables and illustrations taken from medical journals, scientific publications, etc. used in the material must be reproduced loyally, and the exact source must be referenced, cf. section 13(3).

The summary of product characteristics (SPC) is considered as the basic documentation of a medicinal product's properties. In addition, scientific studies that have been published in recognised and independent publications, professional journals, etc. may be used as documentation, cf. section 13(4) of the Advertising Order. »Independent« means that the entity publishing the publication or journal has no interest in neither the sale nor any other promotion of medicinal products. Any such studies must have been subject to a prior independent assessment. The information in the advertisement must comply with the SPC, see section 3.1.

The so-called »abstracts« from congresses, etc. and »data on file«[1] generally cannot be used as documentation as they normally would not meet the above-listed requirements. »Data on file« that have been subjected to an independent assessment on a par with the assessment made prior to the inclusion in recognised scientific journals and that have been recognised as reliable by the independent assessment may, however, be used as documentation until corresponding information has been published, publication of the information has been rejected, or new information has overwritten the scientific validity of the material. If the document in question is an ”abstract” about a scientific study that has been published in a recognised and independent scientific journal and it has been subjected to pre-publication independent assessment, it may be used as documentation.

Furthermore, it is also possible to refer to information from medicin.dk and the Institute for Rational Pharmacotherapy which is based on scientific and independent assessments.

The fact that documentation material is included in the application for authorisation of a medicinal product is not in itself sufficient for it to be used as documentation for information about the medicinal product.

5.5 Economic advantages for patient organisations

A patient organisation must publish on its website any economic advantages, including financial sponsorships (moneys) and payments in kind that the organisation has received from pharmaceutical companies, cf. section 21(1) of the Advertising Order. The information must be published on the website in such a way that the value of economic advantages is specified for each pharmaceutical company, cf. section 21(2) of the Advertising Order. The information must be available on the website no later than one month after the patient organisation received

the economic advantage and must remain available on the website for at least two years, cf. section 21(3) of the Advertising Order.

A patient organisation means an association of patients and relatives whose aim is to safeguard the interests of the patient group, cf. section 71D of the Danish Medicines Act and section 1(7) of the Advertising Order.

A pharmaceutical company means a company having obtained an authorisation under section 7(1) or section 39(1) of the Danish Medicines Act, with the exception of public hospitals, cf. section 1(4) of the Advertising Order.

5.6. Economic advantages for health professionals

According to section 22(1) of the Advertising Order, economic advantages must not be offered or given to health professionals for advertising purposes or otherwise to promote the sale of a medicinal product, cf. however subsection (2) and sections 24, 26, 29, 31, 36 and 37.

The prohibition in section 22(1) does not extend to gifts of insignificant value when the gift can be used in the recipient's business, cf. section 22(2) of the Advertising Order.

The provision makes it legitimate for pharmaceutical companies to offer gifts in kind to health professionals, provided the gift has insignificant value and can be used in the recipient's business. Both conditions must be met to make it legitimate to give or offer a gift.

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

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

Clinical thermometers, ball pens, mouse pads, calendars or desk pads are examples of gifts that »can be used in the recipient's business«. The same can be said for artwork, architect-designed lamps or radios, but these items fall outside the exception in section 22(2) even though they can well be placed in the health professional’s practice. The exception also does not cover gifts like wine, chocolate or flowers to health professionals on anniversaries or other special days, but covers gifts that can be used naturally in the course of the health professional’s activities.

A gift that is financed significantly by a pharmaceutical company will generally be covered by section 22 of the Advertising Order even when it seems to be given by a third party if the recipient should be able to tell that the pharmaceutical company's involvement is decisive and required for the gift to be transferred to the recipient.

Section 22 of the Advertising Order also extends to »image gifts« from pharmaceutical companies to health professionals. It is thus irrelevant whether or not the gift is linked directly to the promotion of a certain medicinal product since it must be assumed that the company’s interest in offering such economic advantages comes from intentions to promote not only the company but also its products. Therefore, image gifts are also considered to be given for purposes of advertising.

The prohibition in section 22(1) of the Advertising Order covers e.g. gifts in the form of money (pecuniary gifts) to a health professional or a private association of health professionals, including professional societies. This type of gift falls outside the exception in section 22(2). But special rules apply to the payment of direct expenses for hospitality in connection with advertising of and professional information about medicinal products and payment of direct expenses for participation in relevant professional courses, conferences, training and the like, cf. section 26 and 5.7 below.

The rules defining what gifts and other economic advantages may be offered to health professionals are matched by a prohibition that health professionals must not receive or request to receive offers in breach of section 22(1), section 23 and section 24 of the Advertising Order, cf. section 25 of the Advertising Order.

5.6.1. Competitions

Section 23 of the Advertising Order prohibits competitions and prizes targeting health professionals for advertising purposes or otherwise to promote the sale of a medicinal product.

The prohibition of section 23 of the Advertising Order against competitions and prizes targeting health professionals is absolute, regardless of the nature of the competition or the value of the prize. It is irrelevant whether or not the competition held by a pharmaceutical company is linked directly to the promotion of a certain medicine. A competition launched at health professionals as part of a company's »image management« activities must be assumed to come from intentions to promote not only the company but also its products. Therefore, the competition must be assumed to have been conducted for advertising purposes in breach of the provision.

5.6.2. Remuneration for professional services

The prohibition in section 22(1) against offering economic advantages to health professionals does not extend to the remuneration of the services of health professionals or pharmacies when such remuneration is proportionate to the service offered, cf. section 24(1). Both the giver and recipient of remuneration must, on request, present the basis for determining the size of remuneration to the Danish Health and Medicines Authority, cf. section 24(1) of the Advertising Order. Remuneration 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 24(2) of the Advertising Order.

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

Doctors, dentists, nurses and proprietor pharmacists must apply for authorisation of or notify their affiliation with a pharmaceutical company when they receive payment for a professional service under section 24(1), according to

the rules of section 202A of the Danish Health Act and Executive Order no. 1154 of 22 October 2014 on Health Professionals' Affiliation with Pharmaceutical Companies, Medical Device Companies and Medical Device Specialty Stores. Veterinarians should be familiar with the rules of section 8A of the Danish Veterinarian Act.

5.6.3. Payment for advertising space

A pharmaceutical company can pay for advertising space at a pharmacy. This could be rental fees for window space to advertise for a medicinal product in a pharmacy, on a monitor in the pharmacy, advertisements in a pharmacy journal or similar. The rental fee for advertising space in a pharmacy must not exceed the market price for corresponding advertising space, and the fee must not be dependent on the pharmacy's sales of the medicinal product, cf. section 24(4) of the Advertising Order. Payment must be effected as a direct payment only, not through off-setting, transfer of benefits in kind or other indirect means, cf. section 24(2) of the Advertising Order. These rules apply equally to rental fees for advertising space in a shop that sells non-pharmacy OTC medicinal products or medicinal products for production animals, cf. section 34 of the Advertising Order.

5.7. Hospitality and sponsorship, etc.

The prohibition described in 5.6 of section 22(1) against giving or offering economic advantages to health professional is modified by a number of explicit exceptions with regard to sponsorship and hospitality in section 26 of the Advertising Order.

Section 26(1) of the Advertising Order allows the giving or offering of the below listed economic advantages to health professionals:

1) Hospitality in the form of payment of direct expenses for meals, travel, accommodation, etc. in connection with advertising of or professional information about medicinal products, and

2) Professional information and training in the form of payment of direct expenses in connection with professionally relevant courses, conferences, supplementary training, etc. attended or conducted by health professionals. Included in these activities must be medicinal product information or other professionally relevant information of professional relevance to the participants.

The provision in section 26(1)(i) gives health professionals the opportunity of sponsorship of direct expenses for meals, travel, accommodation, etc. in connection with advertising of or professional information about medicinal products. This also applies to hospitality in connection with participation in courses and other professional activities involving pharmaceuticals and pharmacy matters.

The provision in section 26(1)(ii) gives health professionals the opportunity of sponsorship of direct expenses for courses and other professional activities, e.g. fees paid to external speakers, course fee expenses, or expenses to buy course material.

5.7.1. Level and extent

The services mentioned in section 26(1)(i) must be reasonable in level and must be strictly limited to the main purpose of the promotional or professional activity, cf. section 26(2) of the Advertising Order. This implies that

events such as a full day seminar from 9:00 to 17:00 may include breakfast on arrival, lunch and possibly a light dinner to close the seminar. Hospitality must not be offered to anyone else than health professionals, cf. section 26(2) of the Advertising Order. The spouse or cohabiter of a health professional may participate on a trip as part of an event held by a pharmaceutical company, provided the spouse or cohabiter pays for all expenses associated with his or her participation. Anyone who pays the expenses under section 26(1)(i) of a health professional must, on request of the Danish Health and Medicines Authority, present to the Authority information on the background for paying the expenses, cf. section 26(2) of the Advertising Order.

Likewise, anyone who pays the expenses under section 26(1)(ii) must, on request of the Danish Health and Medicines Authority, present to the Authority information on the background for paying the expenses, cf. section 26(3) of the Advertising Order.

5.7.2. Events held abroad

If promotional or professional activities are held abroad, the benefits mentioned in section 26(1) may only be paid if the reason for having the event abroad is justified in substantive, practical or financial circumstances of significance, cf. section 26(4) of the Advertising Order.

It could well be the case that it is considerably cheaper to send a group of health professionals to an event abroad than it would be to set up a similar event at home.

The circumstances of significance that justify holding an event abroad must, on request, be presented to the Danish Health and Medicines Authority, cf. section 26(4) of the Advertising Order.

5.7.3. Notification to the Danish Health and Medicines Authority

Health professionals must notify the Danish Health and Medicines Authority if they receive payment for expenses under section 26(1) in connection with participating in professional activities abroad. Notification must be submitted electronically using a form placed on the website of the Danish Health and Medicines Authority, cf. section 27(1) of the Advertising Order.

The notification must include the following details: 1) identification of the health person, 2) identification of the company having paid the expenses pursuant to section 26(1), 3) identification of the organiser of the professional activity if this is not the company having paid the expenses pursuant to section 26(1), 4) information about the professional activity, and 5) the end-date of the activity, cf. section 27(2) of the Advertising Order.

The information mentioned in section 27(2) is published on the website of the Danish Health and Medicines Authority and will be deleted from the website two years after the activity ended, cf. section 27(3) of the Advertising Order.

When a pharmaceutical company promises a health professional to pay the expenses under section 26(1) for that person’s participation in professional activities abroad, it must make the person aware of the rules in section 27 of the Advertising Order and sections 202B and 202C of the Danish Health Act, including the person’s duty to

notify the Danish Health and Medicines Authority and the Authority's publication of information about the affiliation, cf. section 28 of the Advertising Order. This information can be given orally or in writing.

The same applies to persons, covered by sections 34 and 35 of the Advertising Order if they receive payment for the expenses mentioned in section 26(1) in connection with participation in professional activities abroad.

5.8 Public meetings

Pharmaceutical companies are permitted to sponsor meetings that provide professional information about medicinal products to the public hosted by health professionals and pharmacies, cf. section 29(1) of the Advertising Order. Such events may also include information about health and disease.

The amount paid in sponsorship must not exceed the direct expenses related to the hosting of the event in question, cf. section 29(2) of the Advertising Order.

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

Representatives from the sponsor company are not allowed to participate actively at the event, cf. section 29(2) of the Advertising Order. If a proprietor pharmacist was to host an information meeting about medical treatment of diabetes, and the meeting is sponsored by a company that has anti-diabetic medicines in its product range, a representative from that company would not be allowed to discuss the company's products, diabetes, diabetic treatment or otherwise participate actively in the holding of the event.

Correspondingly, pharmaceutical companies may sponsor public meetings that provide professional information about medicinal products hosted by owners of shops authorised to sell non-pharmacy OTC medicinal products or medicinal products for production animals when such meetings concern these medicinal products, cf. section 34 of the Advertising Order.

5.9. Entertainment

Pharmaceutical companies must not pay expenses for health professionals' participation in purely social or cultural events, cf. section 30(1) of the Advertising Order. This prohibition is broad and covers payment for tickets to theatre shows, museums, football matches or like activities. The prohibition applies regardless of the size of payment.

Nor must pharmaceutical companies arrange entertainment in conjunction with professional activities covered by section 26(1)(ii), cf. section 30(2) of the Advertising Order.

6. Cost-related discounts – scope and definition

Section 22(1) of the Advertising Order provides that economic advantages must not be offered or given to health professionals for advertising purposes or otherwise to promote the sale of a medicinal product. A discount will

always be of economic advantage to the recipient, and therefore discounts may generally not be offered to health professionals.

In the meantime, the prohibition does not apply to medicinal product discounts if any such discount is based on supplier cost reductions and is a direct result of a purchase behaviour exhibited by the recipient, which differs from the supplier's standard terms. Such discounts are called »cost-related discounts«, cf. section 36 of the Advertising Order.

The right to offer cost-related discounts covers all medicinal products and concerns all retail distributors of medicinal products, including pharmacies.

The rules on the right to offer cost-related discounts apply solely to the relationship between supplier and retail distributor, regardless of whether the supplier is a pharmaceutical manufacturer, importer or wholesaler. Any discounts between other companies in the supply chain, e.g. between manufacturer/importer and wholesale distributor fall outside the scope of the rules on cost-related discounts. Manufacturers and importers of medicinal products who themselves undertake the delivery of products to retail distributors are covered by all rules on cost-related discounts in respect of these activities.

Cost-related discounts must be settled based on the suppliers' direct and indirect costs associated with delivering medicinal products to pharmacies or other retail distributors, e.g. costs related to administration, wages, storage, delivery vans, etc.

Cost-related discounts could be granted as part of an agreement on fewer deliveries and larger volumes/orders per delivery. This way, the supplier saves costs, partly in response to reduced delivery costs, and partly because of a proportionate fall in administration costs of handling the deliveries. If a retail distributor agrees to change his five weekly deliveries to one weekly delivery, then the basis to offer a discount is secured – provided that the supplier’s standard terms are five weekly deliveries.

Furthermore, the retail distributor may demonstrate flexibility as regards the time of delivery. This could have relevance for proprietor pharmacists who have their own stock of medicinal products, as they might be willing to accept certain irregularities in the supplier’s delivery times. This would make it possible for the supplier to arrange a delivery schedule that is expedient and costs-saving for him.

The purchase behaviour – on which the granting of discounts is based – may be exhibited by one retail distributor alone or a group of retail distributors in unison. This means that supplier cost savings that are based on e.g. the purchase pattern of a group of proprietor pharmacists could form the basis for offering discounts.

Discounts cannot be offered if based solely on changed circumstances on the discount provider's side (e.g. the wholesaler). As mentioned, cost-related discounts assume that the retail distributor exhibits a certain rational purchase behaviour, and it cannot be based on other general rationalisation measures on the discount provider's side, e.g. the introduction of new cost-cutting technology in the wholesale supplier link would not be accepted.

The Advertising Order does not obligate suppliers to offer discounts, but does obligate suppliers to use the same principles to calculate discounts to recipients who exhibit the same purchase behaviour, cf. section 36(2) of the

Advertising Order. It follows that suppliers who calculate discounts to recipients with the same purchase behaviour must apply the same principles to state the cost saving used as basis for discounts. In other words, recipients with the same purchase behaviour have equal possibilities of earning the same discounts for medicinal products whose handling costs are the same.

A discount that is offered under the delivery terms of a specific product number must be assumed to be available also for other product numbers delivered on the same terms. Therefore, it will not be possible for discounts to vary from product number to product number for medicines with the same handlings costs in the same delivery.

A special agreement between wholesaler and manufacturer on cost-effective utilisation of storage capacity at the wholesaler would not justify the wholesaler to offer pharmacies a special discount on products from this manufacturer. On the other hand, varying discounts would be permitted for different products with different delivery requirements, e.g. requirements for specific storage conditions. If a supplier offers varying discounts on different medicinal products in the same delivery, the supplier must be able to justify this in special differences between the medicinal products.

Discounts, price reductions, etc. in one link of the supply chain cannot be considered as cost savings in relation to specific deliveries in subsequent distribution links. Any savings that suppliers make from purchasing medicinal products from manufacturers cannot be passed on as discounts to retail distributors. Thus, it is prohibited to offer discounts that depend on the suppliers' purchase prices and profit margins, which may vary between individual manufactures and products.

Discounts and cost savings must be proportionate, cf. section 36(2) of the Advertising Order. Consequently, discounts must not exceed the cost savings achieved by the supplier from supplying the medicinal products. However, the Advertising Order does not obligate suppliers to pass on the full cost savings achieved as discounts.

The discount must reach no one else than the direct buyer of the medicinal product, cf. section 37, 2nd sentence of the Advertising Order, i.e. the proprietor pharmacists and other retailers who through rational purchase behaviour contributed to the supplier's cost saving. The discounts must not be passed on to others.

Voluntary associations of pharmacies – pharmacy chains – may negotiate agreements on cost-related discounts on behalf of the pharmacies. However, any discounts achieved must be passed on to the pharmacies immediately and must not accumulate in the chains, cf. section 43 of the Advertising Order. Thus, pharmacy chains are not allowed to keep a proportion of the discounts, and the discounts may not remain with the chains longer than necessitated by normal administrative routines, e.g. in connection with bank transfers and the issuing of invoices and credit notes.

The discount must reflect a reduction in the price of the products included in the delivery that triggered a discount, cf. section 37 of the Advertising Order. It will be considered a breach of the rules if suppliers offer discounts by means of other economic advantages than a reduction in the price of the concerned products. Any cost-related discounts must appear clearly from the invoice or credit note issued immediately after delivery of the products, with details of how the discount was calculated, and be separated from other discounts, e.g. discounts on freely traded goods also sold in the pharmacy.

6.1. Special rules on the duty to display information, documentation, management statement and review of discounts on pharmacy-only medicinal products

Special supplementary rules regulate the granting of cost-related discounts on pharmacy-only medicinal products.

Anyone offering cost-related discounts on pharmacy-only medicinal products must publish information about the pharmacies' access to obtaining such discounts, cf. section 71B(2) of the Danish Medicines Act. (duty to display information).

The duty to display information is designed to ensure openness and transparency of suppliers' offering of cost-related discounts on pharmacy-only medicinal products so that the offering of discounts refers to an informed basis. The duty to display information implies that pharmacies are informed of the discounts that are generally available on the market. It allows pharmacies to assess whether the accessible discounts have been obtained and whether any discount granted is in excess of what is cost-related.

Openness and transparency of discount schemes are counterbalanced by the regard for competition interests in the industry. The duty to display information means that suppliers publicly reveal one of their competitive parameters, which might inhibit competition. When defining the rules on the duty to display information, an important element has been to keep in balance the need for openness in discount schemes and the maintenance of competition in the industry.

The provisions in section 38 of the Advertising Order on the duty to display information about cost-related discounts set the framework for the suppliers' publication of information. The rules about the suppliers' display of information are not exhaustive. It is up to the individual supplier of medicinal products to define the content of displayed information since they are basically the ones who know the terms and costs associated with the supply of medicinal products.

The framework implies that the supplier must display the standard terms of delivery that is the basis for his general pricing when no discount is offered. In this connection, the supplier is required to disclose the general circumstances related to the delivery of pharmacy-only medicinal products. e.g. information about the frequency of delivery, the volume/quantity needed in the delivery and whether certain delivery times are required.

In addition to this, the supplier must display any deviations from the standard terms that are eligible for discounts. Such deviations could be in the form of less frequent deliveries, increased delivery volumes/quantities or flexible times of delivery.

Any stated deviations must include the size of discount granted for each deviation. The supplier must publish the maximum level of discount for each type of deviation, just as the supplier can display the discount level related to a combination of several different deviations from the standards terms. The discount granted for the different types of deviations must be stated in a fixed amount, percentage rate or within an interval. The interval for the discount specified does not imply that the suppliers are required to offer a discount within the interval to the pharmacies. .

The information must be published clearly and be easily accessible on the website of the supplier, cf. section 38(1) of the Advertising Order.

It should be noted that pharmacies must not request or receive discounts other than those the supplier may legitimately provide, cf. section 71B(4) of the Danish Medicines Act.

Special requirements apply to the preparation and storing of documentation for any cost-related discounts offered or received and to supplier cost savings when pharmacy-only medicinal products are delivered to pharmacies. Discount providers as well as pharmacists are required to keep evidence of any discounts offered and received for a period of three years, cf. sections 39 and 40 of the Advertising Order. Documentation in the form of invoices, credit notes and other appended material must, on request, be presented to the Danish Health and Medicines Authority, which may also order a discount provider to document that discounts have been granted in compliance with the rules, cf. section 71B(5) and (6). Credit notes involving cost-related discounts may not be issued later than 30 days after the delivery took place. The credit note must clearly specify the deliveries covered. Medicinal product suppliers must ensure that the documentation under section 39 of the Advertising Order is stored such that it is possible for each pharmacy's deliveries to establish a clear link between the information about the access to discounts (the duty to display information) and the invoice/credit note, including information on how the discount is composed and calculated.

In addition, suppliers of medicinal products must prepare special management statements in respect of the granting of cost-related discounts on pharmacy-only medicinal products. The management statement must specify that the discounts have been offered in compliance with the information, prepared and published by the supplier, about the access to obtaining cost-related discounts, cf. the duty to display information, and that the discounts have otherwise been granted in compliance with the Advertising Order, cf. section 41 of the Advertising Order. Similar rules on management statements in regard to received discounts apply to proprietor pharmacists and pharmacy chains, cf. the Executive Order on Proprietor Pharmacists' and Pharmacy Chains' Presentation of Financial Statements.

The supplier's offering of cost-related discounts on pharmacy-only medicinal products must be subject to an audit conducted by a state-authorised accountant or registered public accountant, cf. section 42 of the Advertising Order. The audit includes a test to see whether the stored documentation on cost-related discounts complies with the provisions of the Advertising Order. The audit moreover includes a test to see whether the discounts have been offered in compliance with the information, prepared and presented by the supplier, about the access to obtaining cost-related discounts, cf. the duty to display information, and whether the cost-related discounts have otherwise been granted in compliance with the Advertising Order. The detailed content of the audit appears from audit instructions prepared by the Danish Ministry of Health in cooperation with the Institute of State Authorized Public Accountants in Denmark and the Danish Association of Registered Public Accounts. The audit report is to be composed according to the template in the Advertising Order's Schedule 1 for audit reports regarding medicinal product suppliers' offering of cost-related discounts.

Similar rules on the audit of received discounts apply to proprietor pharmacists and pharmacy chains, cf. the Executive Order on Proprietor Pharmacists' and Pharmacy Chains' Presentation of Financial Statements.

6.2 Price crediting and returning of medicinal products from pharmacy to wholesale distributor

Price crediting is allowed, regardless of the Advertising Order's section 22(1). Price crediting means the situation in which a company authorised under section 39(1) of the Danish Medicines Act compensates a pharmacy for a decline in value of a stocked medicinal product that occurs if the pharmacy purchase price notified to the Danish Health and Medicines Authority is reduced, cf. section 31(1) of the Advertising Order.

However, a company is only allowed to credit a pharmacy a maximum of 30 packages of a medicinal product in a given pack size, pharmaceutical form and strength (i.e. per product number) per price period of 14 days, cf. section 31(2) of the Advertising Order.

A pharmacy is only allowed to return a maximum of 30 packages of a medicinal product in a given pack size, pharmaceutical form and strength (i.e. per product number) per price period of 14 days, cf. section 31(1) of the Advertising Order. However, the provision of subsection (1) does not apply if 1) the medicinal product has been recalled by the company placing it on the market, or 2) the marketing authorisation has been suspended or withdrawn by the Danish Health and Medicines Authority or the European Commission, cf. section 32(3) of the Advertising Order.

Pharmacies must only return purchased and supplied medicinal product packs to the wholesaler having supplied the packages to the pharmacy, cf. section 32(2) of the Advertising Order.

6.2. Bonuses, etc. to users of medicinal products

Bonuses or other economic advantages must not be paid or offered to users of medicinal products in connection with the sale of a pharmacy-only medicinal product, cf. section 71A, 1st sentence, of the Danish Medicines Act. The users could be individual medicine users or groups of medicine users, e.g. a patient organisation.

However, a special exception permits the payment of bonus to hospital owners in connection with the sale of medicinal products to hospitals, cf. section 71A, 2nd sentence, of the Danish Medicines Act.

7. Homeopathic medicinal products

7.1. Homeopathic medicinal products registered according to simplified procedure

The Advertising Order includes special rules on homeopathic medicinal products registered according to a special simplified procedure. The simplified procedure is, among other things, characterised by the fact that there is no documentation on the effect of the medicinal product.

Nor do these medicinal products have a summary of product characteristics (SPC). For this reason, the general rules that advertising should be based on the concerned medicinal product's SPC do not fully apply.

Section 14 of the Advertising Order specifies the information that must and can be present in advertisements for human and veterinary homeopathic medicines. The advertisements must include no other information, but may include general advertising statements, images and the like.

The provisions of the Advertising Order's section 4 about surreptitious advertising, section 10 which specify a number of specific restrictions on the form allowed for advertisements to the public, and sections 20-37 about economic advantages, hospitality and sponsorship, etc. and discounts, apply to homeopahtic medicines on a par with other medicinal products.

7.2. Other homeopathic medicinal products

In case a homeopathic medicinal product is authorised pursuant to the general rules of the Danish Medicines Act, i.e. by a marketing authorisation issued by either the Danish Health and Medicines Authority or the European Commission, the general rules on advertising would apply to this medicinal product.

8. The internet

8.1. Advertising on the internet

Advertising of medicinal products on the internet must satisfy the same requirements as advertisements in other media. However, the rules must as necessary be read and interpreted by taking into account the special characteristics of the internet, cf. section 9(1) of the Advertising Order.

The rules apply to banner ads, internet advertising and the like which clearly take the form of advertising and to the mention of medicinal products on e.g. pharmaceutical company websites when such mention must otherwise be considered to fall under the definition of advertising, see section 2 above ‘Definition of advertising and scope of rules’.

The advertising rules distinguish between advertising to the public and advertising to health professionals. Advertising on the internet, which is accessible to all, must comply with the requirements for advertising to the public.

The rules on advertising to health professionals apply to internet pages available only to health professionals and persons in the business of selling medicinal products in a non-pharmacy context, cf. section 9(3) of the Advertising Order.

Such pages shall be securely access restricted to certain groups of persons through a personal password, cf. section 9(3) of the Advertising Order. It is not sufficient for users to simply enter a password which might even be the same used by all users. The minimum requirement is user identification by means of a unique user name, authorisation ID, or similar, linked with an individual password. It could be a special system used on the website in question or a general system, e.g. the user's digital signature. It is the party responsible for the advertisement that must ensure efficient access restriction so that only the persons mentioned in section 9(3) can access the page. On Facebook, the party responsible for the advertisement can create a page that is closed to the public and give health professionals access on an individual basis. Anyone responsible for an advertisement should also be familiar with the rules in section 6 of the Danish Marketing Practices Act on unsolicited marketing purposes distributed to specific recipients by electronic mail. Reference is made to the Danish Consumer Ombudsman's guidance paper thereon.

8.2. Compulsory information

Advertisements for medicinal products must include a number of compulsory details, cf. sections 5 and 11 of the Advertising Order. On the internet, which allows the linking of several pages, the requirement for posting compulsory information can be met by inserting a link in the advertisement to a separate page that contains the compulsory information. The advertisement must clearly indicate that the link gives access to further information.

9. Medical sales representatives

9.1. Definition and training

Medical sales representatives mean persons who, on behalf of pharmaceutical companies or the like, provide information about and promote medicinal products to health professionals and businesses authorised to sell medicinal products.

Medical sales representatives must have completed adequate training and possess sufficient scientific knowledge enabling them to give precise and adequate information about the medicinal products they promote, cf. section 18(1) of the Advertising Order.

The training may either have been completed at the company they represent or other company or obtained through special programmes, e.g. the medical sales representative programme "Danish Pharmaceutical Academy" offered by the Danish Association of the Pharmaceutical Industry. It is the company's responsibility that the representatives they employ or engage have been given adequate training to ensure they possess the required scientific knowledge about the company’s products.

The activities of medical sales representatives are basically covered by the general rules on medicinal product advertising, including the requirement that advertising must provide adequate and objective information and must not be misleading.

9.2. Availability of summary of product characteristics, etc.

According to section 18(2) of the Advertising Order, medical sales representatives must for each promoted medicinal product have the summary of product characteristics (SPC) available for the person whom they visit with a reference to the current price at medicinpriser.dk (if it is a pharmacy-only medicine) and information about reimbursement status.

The SPC presented must include the content (including wording and set-up) authorised by the Danish Health and Medicines Authority or the European Commission, but could well be incorporated into more extensive product information as long as the SPC can be separated from the extra information.

9.3. Reporting of adverse reactions

If a medical sales representative, from the persons he visits, receives information about the use of one of the promoted medicinal products, including information about adverse reactions, he must report this information to the marketing authorisation holder, cf. section 19 of the Adverse Reactions.

10. Supply of medicinal product samples

10.1. Supply to the public

The supply of free samples of medicinal products to the public is prohibited. In case the supply is not for promotional purposes, the Danish Health and Medicines Authority may authorise it, cf. section 67(1) of the Danish Medicines Act. It is noted in the explanatory notes to the Danish Medicines Act that the Danish Health and Medicines Authority is assumed to exercise extreme caution when permitting the supply of free samples of medicinal products to the public. The provision makes it possible to allow the supply of free medicinal products, e.g. for information purposes.

10.2. Supply to health professionals

The Danish Minister of Health lays down rules on the extent to which medicinal products may be supplied to health professionals, cf. section 67(2) of the Danish Medicines Act. Pursuant to section 1 of the Executive Order on the Supply of Medicinal Products Samples, free samples of medicinal products may only be supplied on the following terms:

1) Medicinal products samples may be supplied only to doctors, dentist and veterinarians and only to the extent that these persons are entitled to prescribe the medicinal product, and its use is permitted in the course of the activities pursued as as doctor, dentist or veterinarian.
2) Only one sample of each medicinal product must be supplied in any one year to any one doctor, dentist or veterinarian. If the medicinal product is available in several pharmaceutical forms and strengths, one sample of each form and strength may be supplied.
3) The medicinal product sample must be no larger than the smallest pack available on the market.
4) The pack must be labelled »Free medicinal product sample – not for resale«.
5) Medicinal product samples must be supplied only in response to a written request, signed and dated, from the recipient.
6) Medicinal product samples may only be supplied by the marketing authorisation holder or a representative. Samples must not be supplied from a pharmacy.
7) Every medicinal product sample must be accompanied by the medicine's summary of product characteristics.
8) Samples of medicinal products covered by the Danish Act on Euphoriant Substances must not be supplied.

The marketing authorisation holder or representative must keep a record of the number of supplied medicinal product samples for each medicinal product, broken down by pharmaceutical form and strength. These records, including the written requests from the recipients, must be stored for at least two years and during that period be available to the Danish Health and Medicines Authority, cf. section 2 of the Executive Order on the Supply of Medicinal Products Samples.

Samples of medicinal products must be used only by doctors, dentists or veterinarians in their respective practices, cf. section 4 of the Executive Order on the Supply of Medicinal Products Samples.

A sample can be supplied only in response to a written request from a doctor. The request must be dated and signed by the doctor. A signature by the doctor's secretary would not be sufficient.

11. Enquiries, complaints and legal recourse

11.1. Enquiries and complaints

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

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

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

11.2. Complaints about advertisements on radio and TV

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

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

12. Self-regulatory bodies

12.1. The relationship between the Danish Health and Medicines Authority and self-regulatory bodies

The supervisory activities of the Danish Health and Medicines Authority involving advertising are supplemented by trade specific self-regulatory bodies that monitor the legitimacy of advertising activities in parallel and collaborate with the Danish Health and Medicines Authority. There are five self-regulatory bodies: The Ethical Committee for the Pharmaceutical Industry (Etisk Nævn for Lægemiddelindustrien, ENLI), the Marketing Board of the Danish Association of the Veterinary Pharmaceutical Industry (VIF's Markedsføringsnævn), the Danish Pharmacy Committee (Apotekernævnet), the DMA Ethical Council (Lægeetisk Nævn), and the Ethical Board of the Danish Association of Suppliers to the Health Industry (Helsebranchens Leverandørforenings Etiske Nævn).

Even though a complaint about an advertisement falls under the activities of one of the self-regulatory bodies, a complainant can always complain directly to the Danish Health and Medicines Authority. When the Danish Health and Medicines Authority reviews a complaint, it may obtain an opinion from the relevant self-regulatory body.

A decision made by a self-regulatory body cannot as such be referred to the Danish Health and Medicines Authority. But a discontented complainant is not prevented from referring a case to the Danish Health and

Medicines Authority, even if it has been investigated by a self-regulatory body. In such scenario, the decision of the self-regulatory body will be included in the Danish Health and Medicines Authority's review of the case.

12.2. The Ethical Committee for the Pharmaceutical Industry (Etisk Nævn for Lægemiddelindustrien)

The Ethical Committee for the Pharmaceutical Industry (ENLI) monitors that the pharmaceutical companies affiliated to ENLI comply with the advertising rules and industry-specific ethical rules, which are compiled in special industry-specific codes of ethics. These are rules that regulate the pharmaceutical companies' collaboration with and information to health professionals, decision-makers, patient organisations and hospitals.

ENLI thus checks that the codes of ethics are observed by the affiliated companies, and ENLI has powers to sanction any violation of the codes of ethics. These checks mainly take place by investigating randomly selected advertising activities directed at health professionals, which the affiliated pharmaceutical companies have a duty to notify to ENLI. The activities are defined as follows:

- All professional events targeting Danish health professionals, either organised or sponsored by the company, including health professionals' participation in any such events as well as the purchasing of exhibition stands for professional events in Denmark.
- All information and advertising material, printed and electronic, regardless of media.

In addition, ENLI handles complaints about affiliated companies received from other companies affiliated to ENLI, authorities, health professionals and others with a significant and creditable interest. Complaints can be made about violation of any of the rules under ENLI's authority. ENLI may also investigate cases on its own initiative in response to media coverage or the like. Finally, ENLI offers, against the payment of a fee, to pre-assess the activities of affiliated companies that want to ensure compliance with the rules, e.g. collaborative agreements, donations and sponsorships, advertising material, etc. Advertising to the public falls outside the authority of ENLI.

Enquiries to ENLI should be directed to Etisk Nævn for Lægemiddelindustrien, Lersø Park Allé 101, 2100 Copenhagen Ø, Denmark, Sekretariat@enli.dk.

12.3. The Marketing Board of the Danish Industrial Association of Veterinary Medicine (Veterinærmedicinsk Industriforening (VIF), Markedsføringsnævnet)

The Marketing Board of the Danish Industrial Association of Veterinary Medicine handles cases about advertising activities related to veterinary medicines according to the statutes of the Board.

According to the statutes of the Marketing Board, the board must consider written complaints from its member companies about marketing activities of other member companies in regard to registered veterinary medicines as well as complaints from anyone who prescribes, distributes, uses or dispenses the members' medicinal products in Denmark. The Marketing Board may furthermore handle complaints from the Danish Health and Medicines Authority about advertising activities of member companies. In addition, the Marketing Board reviews requests from members for pre-approval of specific statements to be used in advertising. The Marketing Board may sanction any violation of the advertising rules by its members. Finally, the Marketing Board reviews complaints

from members of the Danish Industrial Association of Veterinary Medicine about advertising activities launched by veterinary medical companies that are not members of the Association with the view to submitting complaints to the Danish Health and Medicines Authority.

Enquiries should be directed to VIF, Markedsføringsnævnet, Strødamvej 50 A, 2100 Copenhagen Ø, Denmark vif@vif.dk.

12.4. The Danish Pharmacy Committee (Apotekernævnet)

The Danish Pharmacy Committee supervises that pharmacies comply with the Code of Collaboration Between Pharmacies and the Pharmaceutical Industry.

The Danish Pharmacy Committee supervises the pharmacies' compliance with this code by pre-assessing specific collaborative ties and by handling complaints from pharmacies, medicinal product suppliers, etc. which have a special and reasoned interest in the case in question. The committee may also open cases on its own initiative.

Enquiries should be made to Apotekernævnet, Sekretariatet, Kanonbådsvej 10, 1437 Copenhagen K, Denmark, apotekernaevnet@apotekernaevnet.dk.

12.5. The DMA Ethical Council (Lægeetisk Nævn)

The DMA Ethical Council ensures, among other things, that the professional collaboration between doctors and the pharmaceutical industry takes place according to the applicable rules of ethics (the Danish Medical Association's code of ethics).

The council handles complaints received by members of the Danish Medical Association. The council may also open cases on its own initiative. Enquiries should be made to the DMA Ethical Council (Lægeetisk Nævn), Kristianiagade 12, 2100 Copenhagen Ø, Denmark.

12.6. The Ethical Board of the Danish Association of Suppliers to the Health Industry (Helsebranchens Leverandørforenings Etiske Nævn)

The Ethical Board of the Danish Association of Suppliers to the Health Industry assesses advertising cases that violate legislation and its own ethical code. The Ethical Board can open cases on its own initiative, just as the board of directors and the members of the Association of Suppliers to the Health Industry may request the Ethical Board to assess a case.

The Ethical Board can only assess cases that concern the members of the Danish Association of Suppliers to the Health Industry. However, the Ethical Board can make statements in cases of principle, even in cases that have no direct connection to the members of the Danish Association of Suppliers to the Health Industry.

Enquiries should be made to Helsebranchens Leverandørforening, Børsen, 1217 Copenhagen K, hbl@hts.dk.

13. Previous guideline

Guideline no. 10355 of 22 December 2014 on Advertising, etc. of Medicinal Products is repealed.

Henrik G. Jensen

Official notes

[1)] »Data on file« means a conclusive and signed study report, in which the results of the study are accounted for, generated through statistical processing of data according to the protocol. Detailed results, including individual data, must appear from one or more appendices. A synopsis of the report must concisely, yet exhaustively, describe the design, treatment, patient material and most important results. The reference to the report must include the full report title and study code, the name of the principal investigator and medically responsible person as well as year and company name.