Guideline no. 9401 of 20 April 2022

Danish Ministry of Health

Guideline on Advertising, etc. of Veterinary Medicinal Products

1.Veterinary Medicinal Products Advertising rules

The rules on advertising of veterinary medicinal products are found in articles 119-121 of Regulation (EU) no. 2019/6 on Veterinary Medicinal Products (the Veterinary Medicinal Products Regulation), Part VII (sections 67-70) of the Danish Medicines Act and Executive Order no. 130 of 25 January 2022 on Advertising etc. of Veterinary Medicinal Products. These rules are mentioned in this guideline.

Furthermore, the Executive Order on Advertising etc. of Veterinary Medicinal Products lays down rules on veterinary 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 veterinary medicinal products. These rules are also mentioned in this guideline.

2. Definition of advertising and scope of rules

2.1. Definition and scope

Advertising of veterinary medicinal products is defined in article 4(40) of the Veterinary Medicinal Products Regulation. Advertising of veterinary medicinal products means the making of a representation in any form in connection with veterinary medicinal products in order to

promote the supply, distribution, sale, prescription or use of veterinary medicinal products and comprising also the supply of samples and sponsorships.

The definition of advertising of veterinary medicinal products is interpreted in a broad manner pursuant to the main purposes of the advertising rules, which are to protect human health and animal welfare. It covers the representation in any form intended to promote the supply, distribution, sale, prescription or use of veterinary medicinal products. In this context, representation means any way in which a medicinal product is displayed or presented with a view to the mentioned purposes. Advertising can cover both oral and written statements. Whether it is advertising of veterinary medicinal products is determined based on an assessment of the circumstances of each individual case, including the nature of the concerned activity carried out and the content of the message. The assessment includes all relevant circumstances of the specific case.

The definition of advertising of medicinal products is not limited to certain senders or media. To be considered advertising, it is not required that a message about a medicinal product is disseminated in relation to commercial activities or that the person disseminating the message about a medicinal product is affiliated to the pharmaceutical company/marketing authorisation holder. Both pharmaceutical companies and others can be the sender of advertising of veterinary medicinal products.

Any affiliation to a pharmaceutical company is included in the assessment of existence of advertising together with other relevant circumstances. If, for example, an employee of a pharmaceutical company shares or likes an advert for one of the company's medicinal products, or if the employee, for example, shares and likes other material containing claims or other positive mention of the medicinal product, on a social media, this may be considered advertising of the medicinal product even if the person is acting on his own. The assessment will be based on the nature of the activity carried out, the content of the message, the employee's affiliation to the

company and any other relevant circumstances. To be considered advertising of a medicinal product, the material does not have to be in the format of typical advertising, e.g. an advert, the reason being that the definition of advertising is not limited to certain formats. Nonetheless, it will be a factor included with other relevant circumstances to determine whether it is advertising. By virtue of their employment relationship, employees have a special connection to the company and that may be a motivating factor for them to share and like information about the company and its medicinal products. An advertisement that both advertises for the pharmaceutical company and one of its medicinal products is also treated as an advertisement for a medicinal product that must comply with the rules on advertising of medicinal products. A company will not be considered responsible for an employee's action (advertising) on a social media if the company did not encourage such action or otherwise took part therein, and the action did not take place in a company context.

It is not considered advertising of a medicinal product if an employee of a pharmaceutical company shares information about one of the company's medicinal products on a social media for another purpose than advertising. For example, someone may do so to promote their own professional competences on LinkedIn, using their profile to share facts about the medicinal product in the description of their professional competences. Likewise, it is not considered advertising of medicinal products if the employee shares general information about the company with a view to promoting the company as a great place to work and drawing attention to good career opportunities on social media.

Influencers and bloggers may, depending on the circumstances, be held accountable for advertising of medicinal products on their profiles and websites. This could, for example, be an influencer who has received payment from a pharmaceutical company for reviewing one of the company's medicinal products on a social media and who makes claims about the medicinal product on a social media on the internet.

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.

The rules on advertising of veterinary medicinal products apply to veterinary medicinal products prepared industrially or by a method involving an industrial process and intended to be placed on the market, cf. article 2(1) of the Veterinary Medicinal Products Regulation.

Article 2(3) of the Veterinary Medicinal Products Regulation stipulates that article 120 also applies to inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals in an epidemiological unit and used for the treatment of that animal or those animals in the same epidemiological unit or for the treatment of an animal or animals in a unit having a confirmed epidemiological link. According to article 120(3), advertising of these medicinal products is prohibited.

It follows from article 2(7) of the Veterinary Medicinal Products Regulation that the regulation does not apply to

1) veterinary medicinal products containing autologous or allogeneic cells or tissues that have not been subjected to an industrial process;
2) veterinary medicinal products based on radio-active isotopes;
3) feed additives as defined in point (a) of Article 2(2) of Regulation (EC) No 1831/2003 of the European Parliament and of the Council;
4) veterinary medicinal products intended for research and development;

5) medicated feed and intermediate products as defined in points (a) and (b) of Article 3(2) of Regulation (EU) 2019/4.

2.2. Exemptions

The rules on advertising of veterinary medicinal products do not apply to:

1) The labelling and package leaflet of veterinary medicinal products, cf. articles 10-14 of the Veterinary Medicinal Products Regulation. It appears from article 13 that the immediate packaging and outer packaging of a veterinary medicinal product must not include advertising. Article 14(2) of the Veterinary Medicinal Products Regulation furthermore provides that the package leaflet must not include information that is promotional.

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 veterinary 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.

4) Price lists, product categories, 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 categories, etc. that are published on the internet for the purpose of selling veterinary medicinal products online.

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

campaign for prevention of disease by means of vaccination, provided that no reference, neither direct nor indirect, is made to specific vaccines.

6) Press releases that give factual and concise details about a veterinary 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. A pharmaceutical company can use a social media to briefly inform the press of a news update available in the press area with an indication of the update's theme in objective terms and possibly a link to the company's homepage or to the press area. It is required that it will appear from the post that it is targeted at the press, e.g. by adding "#PRESS", and that no medicinal product name is included in the post as otherwise it could, based on an individual assessment, be considered as advertising of the medicinal product.

7) Unedited and unabbreviated reproduction of a package leaflet, the approved summary of product characteristics (SPC), a publicly available assessment report, cf. section 56 of the Veterinary Medicinal Products Regulation, 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.

It is not considered to be advertising when a company responds to an enquiry by a veterinarian or another person by sending a scientific article about a clinical trial of a veterinary medicinal product to that person, 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.

3. General provisions

3.1. General requirements for the content and form of advertising of veterinary medicinal products

Article 119 of the Veterinary Medicinal Products Regulation contains the general requirements for the content and form of advertising of veterinary medicinal products. The provisions apply in general to advertising of veterinary medicinal products, including prescription-only veterinary medicinal products.

First of all, the advertising of a veterinary medicinal product must make it clear that it aims at promoting the supply, sale, prescription, distribution or use of the veterinary medicinal product, cf. article 119(2) of the Veterinary Medicinal Products Regulation.

This means that advertising of a veterinary medicinal product must be presented in such manner that it is clear that it is advertising aimed to promote the supply, sale, prescription, distribution or use of the veterinary medicinal product. Any form of surreptitious advertising of a veterinary 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.

Secondly, the advertising must not be formulated in such a way as to suggest that the veterinary medicinal product could be a feed or a biocide, cf. article 119(3) of the Veterinary Medicinal Products Regulation.

Consequently, it is not permitted to use wordings incorrectly suggesting that the veterinary medicinal product could be a feed or biocide.

Thirdly, the advertising must comply with the summary of product (SPC) characteristics of the advertised veterinary medicinal product, cf. article 119(4) of the Veterinary Medicinal Products Regulation. The particulars in the SPC include information about the composition of the veterinary medicinal product, pharmaceutical form, therapeutic indications (applications), contraindications, adverse reactions, precautions for use, dosage, and warnings, if any.

This means that the content of the advertisement must not conflict 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 for a veterinary medicinal product may include statements that supplement the information in the SPC, provided they confirm or clarify information in the SPC and the information otherwise complies with the SPC. For example, this could be documented claims about the effects or adverse reactions of the medicinal product, confirming or clarifying information in the SPC and which comply with the SPC. The information in the advertisement must not be misleading or lead to incorrect use of the veterinary medicinal product. An advertisement for a veterinary medicinal product must only include information about authorised indications as appearing from the authorised SPC.

Fourthly, the advertisement must not include information in any form which could be misleading or lead to incorrect use of the veterinary medicinal product, cf. article 119(5) of the Veterinary Medicinal Products Regulation.

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 veterinary medicinal product must neither in form nor content mislead or be designed to mislead the persons it is aimed at. An overall assessment of the advertisement, including text, images and illustrations, etc. will determine if the advertisement is misleading.

Fifthly, the advertisement must encourage the responsible use of the veterinary medicinal product, by presenting it objectively and without exaggerating its properties, cf. section 119(6) of the Veterinary Medicinal Products Regulation.

This means that an advertisement of a veterinary medicinal product must be factual. Therefore, the medicinal product must not be marketed in the same aggressive and consumption-encouraging manner as general consumer goods. The advertisement must also be based on professional and relevant information about the medicinal product. This implies, for example, that it is not permitted to focus exclusively on the benefits of using the medicinal product, but that the advertisement must generally also include relevant information about, e.g. adverse reactions, contraindications, withdrawal periods, special warnings, and special precautions for use. Advertising of veterinary medicinal products must not be designed to or likely to generate unnecessary increases in the consumption of medicines.

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:

– free consumer goods offered in connection with advertising of veterinary medicinal products to the public.

– competitions and prizes linked to the promotion of veterinary medicinal products.

– advertising of veterinary 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.

Registered homeopathic medicinal products

There is no summary of product characteristics supplied with registered homeopathic veterinary medicinal products. Therefore, the requirement in the Veterinary Medicinal Products Regulation for advertisement to be in accordance with the summary of product characteristics of the advertised veterinary medicinal product does not apply to registered homeopathic medicinal products.

Registered homeopathic medicinal products are registered pursuant to a special simplified procedure that is characterised, for example, by the absence of documentation of the medicinal product's effect. These medicinal products therefore have no therapeutic indications.

Advertising of a veterinary medicinal product must present the medicinal product objectively and without exaggerating its properties, cf. article 119(6) of the Veterinary Medicinal Products Regulation. For this reason, registered homeopathic medicinal products must not be marketed with therapeutic indications. In addition, the advertisement must not include information which could be misleading, cf. article 119(5), which means, for example, that it must not include information incorrectly suggesting that the medicinal product has been authorised for therapeutic indications, or that it has a documented effect relative to specific therapeutic indications.

3.2. Advertising of prescription-only medicinal products

It follows from article 120(1) of the Veterinary Medicinal Products Regulation that the advertising of veterinary medicinal products that are subject to veterinary prescription in accordance with article 34 is allowed only when made exclusively to the following persons:

1) veterinarians;

2) persons permitted to supply veterinary medicinal products in accordance with national law.

This means that advertising of prescription-only veterinary medicinal products is permitted only to veterinarians and to proprietor pharmacists, wholesalers and distributors authorised under the Danish Pharmacy Act or section 39(1) of the Danish Medicines Act to sell, distribute and supply prescription-only veterinary medicinal products.

However, article 120(3) of the Veterinary Medicinal Products Regulation prohibits the advertising of inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals in an epidemiological unit and used for the treatment of that animal or those animals in the same epidemiological unit or for the treatment of an animal or animals in a unit having a confirmed epidemiological link.

3.3. Only authorised or registered veterinary medicinal products may be advertised in Denmark

Article 119(1) provides that only veterinary medicinal products that are authorised or registered in a Member State may be advertised in that Member State.

This means that in Denmark, the advertising allowed concerns only veterinary medicinal products authorised by a marketing authorisation issued by the Danish Medicines Agency or the European Commission and veterinary medicinal products registered by the Danish Medicines Agency.

Additionally, anyone placing a pharmacy-only veterinary medicinal product on the Danish market must notify its price to the Danish Medicines Agency no later than 14 days prior to the price's effective date, cf. section 77(1) of the Danish Medicines Act. Thus, the price can be notified earlier than 14 days before the price is to take effect. To do so, an e-mail must be sent with details of the expected price and effective date to medicinpriser@dkma.dk. For some non-pharmacy medicinal products it is required that their available pack sizes have been notified to the Danish Medicines Agency, also at 14 days' notice, cf. section 78(1) of the Danish Medicines Act.

The provision in article 119(1) implies that it is prohibited to advertise for veterinary medicinal products that are not authorised by a marketing authorisation issued by the Danish Medicines Agency or the European Commission, or which are not registered in Denmark.

If the marketing authorisation of a veterinary medicinal product is suspended, no advertising of the medicinal product in question must take place during the period of suspension, cf. article 119(7) of the Veterinary Medicinal Products Regulation.

3.4. Magistral medicinal products

Article 119(1) of the Veterinary Medicinal Products Regulation provides that only veterinary medicinal products authorised or registered in a Member State may be advertised. Consequently, no advertising of magistral medicinal products is permitted. This prohibition follows naturally from the fact that magistral veterinary medicinal products are prepared for an individual animal on directions from a veterinarian.

Please see section 3.3.

3.5. Special medicinal products

Article 119(1) of the Veterinary Medicinal Products Regulation provides that only veterinary medicinal products authorised or registered in a Member State may be advertised. The rules thus prohibit advertising of:

– Veterinary medicinal products used in accordance with a special authorisation pursuant to article 112 or article 116 of the Veterinary Medicinal Products Regulation, and

– Immunological veterinary medicinal products used in accordance with article 110(2) and (3) of the Veterinary Medicinal Products Regulation,

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 veterinary medicinal product must keep a copy of or other documentation of any form of advertising for a veterinary 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 Medicines Agency on request.

According to section 2(2) of the Executive Order on Advertising etc. of Veterinary Medicinal Products, 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 file content on a computer nor when exchanging 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 veterinary medicinal product must keep information about how the advertisement was used in practice, cf. section 2(3) of the Executive Order on Advertising etc. of Veterinary Medicinal Products:

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 veterinary 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(5) of the Danish Medicines Act, the Danish Medicines Agency 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 Medicines Agency 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 pecuniary advantages beyond what is permitted, cf. article 121 of the Veterinary Medicinal Products Regulation.

3.7. Orders

By virtue of section 69(2) of the Danish Medicines Act, the Danish Medicines Agency may order that any unlawful advertising of a veterinary medicinal product must be withdrawn.

The Danish Medicines Agency 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 Medicines Agency may decide the form, contents and place of the publication, cf. section 69(3) of the Danish Medicines Act.

3.8. Surreptitious advertising

Advertising must be designed such that it is clear that it is advertising and that the advertising aims to promote the supply, sale, prescription, distribution or use of veterinary medicinal products, cf. article 119(2) of the Veterinary Medicinal Products Regulation.

4. Advertising to persons, etc. in certain shops

Owners of or managerial staff in shops authorised to sell non-pharmacy OTC veterinary medicinal products are also governed by the provisions on pecuniary advantages and discounts, etc. of article 121 of the Veterinary Medicinal Products Regulation and sections 3-8, section 13 and section 14 in the Executive Order on Advertising, etc. of Veterinary Medicinal Products, cf. section 12 of the Executive Order on Advertising, etc. of Veterinary Medicinal Products. However, the provisions apply only if the advertising and the pecuniary advantage concern such medicinal products.

5. Documentation

The summary of product characteristics (SPC) is considered as the basic documentation of the information about 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. “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 advertising must comply with the SPC, see section 3.1 above.

The so-called “abstracts” and “posters” from congresses and the like generally cannot be used as documentation as they normally would not meet the above-listed requirements. Thus, it is not sufficient that a study has been subject to an independent assessment prior to an oral presentation at a conference or a symposium. Likewise, publication in abstract books published by a conference organiser or publication on the website of a professional society cannot be equated with publication in recognised and independent scientific journals or the like. 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. The so-called »data on file«[1] generally cannot be used as documentation as they normally would not meet the above-listed requirements for publication and independent assessment prior to publication.

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.

For other information on a medicinal product, e.g. the price of a pharmacy-only medicinal product, reference is made to the current price on medicinpriser.dk.

6. Economic advantages for persons qualified to prescribe or supply veterinary medicinal products

The rules on economic advantages for persons qualified to prescribe or supply veterinary medicinal products apply to health professionals. In this context, health professionals mean veterinarians, pharmacists, pharmaconomists, veterinary nurses and students within these fields, cf. section 1(3) of the Executive Order on Advertising etc. of Veterinary Medicinal Products. The rules also apply to owners of and managerial staff in shops authorised to sell non-pharmacy OTC medicinal products or medicinal products for production animals.

Article 121(1) of the Veterinary Medicinal Products Regulation provides that where medicinal products are being promoted to persons qualified to prescribe or supply them in accordance with this Regulation, no gifts, pecuniary advantages or benefit in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the person's practice of prescription or supply of medicinal products.

The provision generally prohibits the supply, offer or promise of gifts or other pecuniary advantages, including benefits in kind, to persons qualified to prescribe or supply/dispense veterinary medicinal products in connection with the promotion of medicinal products

However, pharmaceutical companies may legitimately supply a gift or other pecuniary advantage in the form of benefits in kind to persons qualified to prescribe or supply/dispense veterinary medicinal products if the gift of benefit in kind is inexpensive and relevant to the person's practice (meaning that it can be used in the recipient's business). "Inexpensive" means gifts and benefits in kind of insignificant value, and "relevant to the person's practice" means a gift or other benefit in kind that can be used in the recipient's business. Both conditions (inexpensive and relevant) must thus be met to make it legitimate to supply or offer a gift or other benefit in kind. Another benefit in kind could, for example, be the lending of equipment that can be used in the veterinarian's practice.

The Regulation does not set a certain limit on the value of such gifts/pecuniary advantages, but, if the total value from one giver to a person qualified to prescribe or supply/dispense veterinary medicinal products does not exceed DKK 300 in a calendar year, such gift/pecuniary advantage can be offered legitimately.

The value is not based on what the giver paid for the gift/pecuniary advantage (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.

Clinical thermometers, ball pens, mouse pads, calendars or desk pads are examples of gifts that are "relevant to the person's practice". The same can be said for artwork, architect-designed lamps or radios, but these items fall outside the exception in article 121(1) even though they can well be placed in the person's practice or business. The exemption clause also does not cover gifts like wine, chocolate and flowers to a person qualified to prescribe or supply veterinary medicinal products, e.g. for anniversaries. The exemption clause covers gifts and other benefits in kind, including the lending of equipment, etc. that may naturally form part of the person's business.

A gift that is financed significantly by a pharmaceutical company will generally be covered by article 121(1) 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.

The provision also extends to “image gifts” from pharmaceutical companies to persons qualified to prescribe or supply/dispense veterinary medicinal products. 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 article 121(1) covers e.g. gifts in the form of money (pecuniary gifts) to a person qualified to prescribe or supply/dispense veterinary medicinal products or to a private association of such persons. This type of gift falls outside the exception in article 121(1). However, special rules apply to the payment of direct or indirect expenses for hospitality in connection with professional events for purely professional and scientific purposes, cf. article 121(3) and section 6.3 herein.

The rules regulating which gifts and pecuniary advantages may be offered to persons qualified to prescribe or supply/dispense medicinal products, is offset by a provision according to which these persons are prohibited from soliciting or accepting any offerings that contravene article 121(1), cf. article 121(2), of the Veterinary Medicinal Products Regulation.

6.1. Remuneration for professional services

The provision in article 121(1) stipulates that in connection with the promotion of veterinary medicinal products no gifts, pecuniary advantages or benefit in kind may be supplied, offered or promised to persons qualified to prescribe or supply/dispense veterinary medicinal products.

This provision 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 3(1) of the Executive Order on Advertising, etc. of Veterinary Medicinal Products.

Payment must be effected as a direct payment only, not through off-setting, transfer of benefits in kind or other indirect means, cf. section 3(2) of the Executive Order on Advertising, etc. of Veterinary Medicinal Products.

6.2. 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 veterinary 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 3(4) of the Executive Order on Advertising, etc. of Veterinary Medicinal Products. Payment must be effected as a direct payment only, not through off-setting, transfer of benefits in kind or other indirect means, cf. section 3(2) of the of the Executive Order on Advertising, etc. of Veterinary Medicinal Products. These rules apply equally to rental fees for advertising space in a shop that sells non-pharmacy OTC medicinal products, cf. section 12 of the Executive Order on Advertising, etc. of Veterinary Medicinal Products.

A pharmaceutical company can also pay for advertising space at a professional society/association consisting of health professionals in connection with a professional event for health professionals. This could for example be an annual conference organised by a professional society consisting of health professionals. Such payment must be proportionate to the service offered (the advertising space), cf. section 3(1) of the Executive Order on Advertising, etc. of Veterinary Medicinal Products. This depends on a specific assessment of the number of

participants at the annual conference and the duration and price (market price) of corresponding advertising space. The payment must not exceed the market price for corresponding advertising space. A price per square metre of DKK 2000, including VAT and administration fee, for a full-day event at a rented, external location accommodating about 50-80 participants would normally be considered proportionate to the service offered. A higher price per square metre can be accepted if the market price is higher due to a larger number of participants or other circumstances.

A pharmaceutical company may also make an agreement with a professional society/association consisting of health professionals on advertising space on the website of the society/association against payment, if the payment is proportionate to the service offered (the advertising space). This depends on a specific assessment of the content and duration of the agreement, the number of website users and the price (market price) of corresponding advertising space. The payment must not exceed the market price for corresponding advertising space.

6.3. Hospitality

The previously mentioned prohibition in article 121(1) against supplying or offering pecuniary advantages to persons qualified to prescribe or supply/dispense veterinary medicinal products is modified by hospitality provisions in article 121(3).

It follows from article 121(3) that it is permitted to offer free hospitality, directly or indirectly, in connection with professional events for purely professional and scientific purposes to persons qualified to prescribe or supply veterinary medicinal products provided that such hospitality is strictly limited to the main objective of the event.

The provision in article 121(3) gives persons qualified to prescribe or supply/dispense veterinary medicinal products the opportunity for sponsorship of meals, travel, accommodation, etc. in connection with purely professional events about medicinal products and other professionally-relevant information.

The provision does not cover events held in connection with advertising of medicinal products. As mentioned, it covers only events “with purely professional and scientific purposes”.

6.3.1. Level and extent

The hospitality must be strictly limited to the main objective of the professional event, cf. article 121(3) of the Veterinary Medicinal Products Regulation. This implies that for example a professional full day seminar from 9:00 to 17:00 may include breakfast on arrival, lunch and possibly a light dinner to close the professional event. Hospitality must not be offered to anyone else than persons qualified to prescribe or supply/dispense veterinary medicinal products. The spouse or cohabiter of a veterinarian may participate on a trip as part of a professional event held by a pharmaceutical company, provided the spouse or cohabiter pays for all expenses associated with his or her participation. Anyone paying for the expenses in accordance with article 121(3) must on request of the Danish Medicines Agency present to the Agency information on the offering and the background for paying the expenses, cf. section 5 of the Executive Order on Advertising, etc. of Medicinal Products.

6.3.2. Notification to the Danish Medicines Agency

Health professionals must notify the Danish Medicines Agency if they receive payment for expenses under article 121(3) in connection with participating in a professionally-relevant activity abroad or in an international professionally-relevant congress or conference in Denmark. Notification must be submitted electronically using a form placed on the website of the Danish Medicines Agency, cf. section 6(1) of the Executive Order on Advertising, etc. of Veterinary Medicinal Products.

The notification must include the following details: 1) identification of the health professional, 2) identification of the company having paid the expenses pursuant to article 121(3) of the Veterinary Medicinal Products Regulation, 3) identification of the organiser of the professionally-

relevant activity if this is not the company having paid the expenses pursuant to article 121(3) of the Veterinary Medicinal Products Regulation, 4) information about the professionally-relevant activity, and 5) the end-date of the activity, cf. section 6(2) of Executive Order on Advertising etc. of Veterinary Medicinal Products.

The information mentioned in section 6(2) is published on the website of the Danish Medicines Agency and will be deleted from the website two years after the activity ended, cf. section 6(3) of the Executive Order on Advertising etc. of Veterinary Medicinal Products.

Please also see the Danish Medicines Agency's guideline no. 9378 of 19 May 2021 for health professionals, including students and certain professionals, on notification of economic support from pharmaceutical companies, medical device companies and companies manufacturing, importing or distributing products not having a medical purpose.

When a pharmaceutical company promises a health professional to pay the expenses under section 121(3) of the Veterinary Medicinal Products Regulation for that person's participation in a professionally-relevant activity abroad or an international professionally-relevant congress or conference in Denmark, it must make the person aware of the rules in section 6 of the Executive Order on Advertising etc. of Veterinary Medicinal Products and sections 202B and 202C of the Danish Health Act, including the person's duty to notify the Danish Medicines Agency and the Agency's publication of the information mentioned in section 6(2), cf. section 7 of the Executive Order on Advertising etc. of Veterinary Medicinal Products. This information can be given orally or in writing. However, the Danish Medicines Agency recommends that information be given in writing for purposes of subsequent documentation.

The same applies to persons, covered by section 12 of the Executive Order on Advertising etc. of Veterinary Medicinal Products if they receive payment for the expenses mentioned in article

121(3) in connection with participation in a professionally-relevant activity abroad or an international professionally-relevant congress or conference in Denmark.

By 31 January of every calendar year, pharmaceutical companies must notify the Danish Medicines Agency of the health professionals and professionals covered by section 12 to which they have offered economic support for participation in professionally-relevant activities abroad and international professionally-relevant congresses and conferences in Denmark. This notification must include health professionals and professionals having received economic support in the preceding calendar year, cf. section 8(1) of the Executive Order on Advertising etc. of Veterinary Medicinal Products. Notification can be submitted electronically using a form placed on the website of the Danish Medicines Agency, cf. section 8(3) of the Executive Order on Advertising, etc. of Veterinary Medicinal Products.

The notification (under subsection 1) must include the following details: 1) The name and CVR number of the pharmaceutical company, 2) The full name, email address, profession as well as authorisation ID or CPR number (civil registration number) of health professionals and professionals, and 3) Information on the professionally-relevant activities, cf. section 8(2) of the Executive Order on Advertising etc. of Veterinary Medicinal Products.

Please also see the Danish Medicines Agency's guideline no. 9380 of 19 May 2021 for pharmaceutical companies, medical device companies and companies manufacturing, importing or distributing products not having a medical purpose on economic support for health professionals including students and certain professionals.

A congress or conference held in Denmark will be considered an "international" congress or conference when several participants or speakers come from outside Denmark. Examples of international professionally-relevant congresses and conferences include international scientific

congresses arranged by international professional scientific societies, or international professional conferences on specific therapeutic areas arranged by international organisations.

7. Cost-related discounts for pharmacies and others.

Article 121(4) of the Veterinary Medicinal Products Regulation stipulates that the rules in articles 121(1)-(3) shall not affect existing measures or trade practice in Member States relating to prices, margins and discounts. By reference to this provision, the Danish rules on discounts are continued, cf. Part V of the Executive Order on Advertising etc. of Veterinary Medicinal Products.

It follows from section 13 of the Executive Order that offering discounts on veterinary medicinal products is allowed if any such discount is based on supplier cost reductions and is a direct result of a purchase behaviour exhibited by the recipient, which deviates from the supplier's standard terms. Such discounts are called “cost-related discounts”.

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

The rules on offering cost-related discounts apply solely to the relationship between supplier, cf. section 1(5) of the Executive Order, 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. That 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.

This 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 Executive Order does not contain an obligation 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 13(2) of the Executive Order on Advertising etc. of Veterinary Medicinal Products. 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 13(2) of the Executive 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 14, 2nd sentence of the Executive 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 20 of the Executive Order on Advertising etc. of Veterinary Medicinal Products. 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 14 of the Executive 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.

7.1. 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 15 of the Executive Order on Advertising etc. of Veterinary Medicinal Products concerning 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 15(1) of the Executive 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 15 and 16 of the Advertising Order. Documentation in the form of invoices, credit notes and other appended material must, on request, be presented to the Danish Medicines Agency, 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 16 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 18 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 19 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.

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

Article 121(4) of the Veterinary Medicinal Products Veterinary Medicinal Products stipulates that the rules in articles 121(1)-(3) shall not affect existing measures or trade practice in Member States relating to prices, margins and discounts. By reference to this provision, the Danish rules on price crediting and returning of medicinal products are continued, cf. sections 9 and 10 of the Executive Order on Advertising etc. of Veterinary Medicinal Products.

Price crediting is permitted pursuant to section 9 of the Executive Order. 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 Medicines Agency is reduced, cf. section 9(1) of the Executive 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 9(2) of the Executive 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 10(1) of the Executive Order. However, the provision of subsection (1) does not apply if 1) the medicinal product has been recalled by the company having placed it on the market, or 2) the marketing authorisation has been suspended or withdrawn by the Danish Medicines Agency or the European Commission, cf. section 10(3) of the Executive Order.

Pharmacies must only return purchased and supplied medicinal product packs to the wholesaler having supplied the packages to the pharmacy, cf. section 10(2) of the Executive Order.

7.3. 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 the individual animal owner, a veterinarian or groups of users of a veterinary medicinal product.

8. Advertising on the internet and social media

Advertising of medicinal products on the internet and social media must satisfy the same requirements as advertising in other media.

The rules apply to banner ads, internet advertising which clearly take the form of advertising and to the mention of medicinal products on e.g. pharmaceutical company websites or on social media 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'.

Any advertising on the internet that is available to everyone cannot include advertising of prescription-only medicinal products. For advertising of prescription-only medicinal products to take place in compliance with the rules of article 120 of the Veterinary Medicinal Products Regulation, such pages shall be securely access restricted to the groups of persons mentioned in article 120(1) (see under 3.2) through a personal password or the like. 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

article 120(1) can access the page. On Facebook, the party responsible for the advertisement can create a page that is closed to the public and give the persons mentioned in article 120(1) access on an individual basis. Anyone responsible for an advertisement must also be familiar with the rules in section 10 of the Danish Marketing Practices Act on unsolicited marketing purposes distributed to specific recipients by electronic mail. Reference is made to the Danish Consumer Ombudsman's guidance paper thereon.

9. Advertising of medicinal products at international congresses and conferences in Denmark

The rules on advertising of veterinary medicinal products also apply to international congresses and conferences in Denmark. This means, among other things, that the prohibition against advertising of medicinal products which are not authorised or registered in Denmark, cf. article 119(1) of the Veterinary Medicinal Products Regulation, a contrario, and the rules on advertising of prescription-only medicinal products, cf. section 120(1), apply also to advertising of medicinal products at international congresses and conferences held in Denmark.

10. Supply of medicinal product samples

Pursuant to article 119(9) of the Veterinary Medicinal Products Regulation, antimicrobial veterinary medicinal products must not be distributed for promotional purposes as samples or in any other presentation.

In respect of other veterinary medicinal products, article 119(8) of the Veterinary Medicinal Products Regulation provides that veterinary medicinal products must not be distributed for promotional purposes except for small quantities of samples.

When dispensing samples, small quantities mean 1-2 packages of a marketed medicinal product in any one year. If the medicinal product is available in several pharmaceutical forms and

strengths, 1-2 samples of each form and strength may be supplied. The medicinal product sample must be in the smallest pack available on the market.

Samples distributed for promotional purposes must be appropriately labelled indicating that they are samples and must be given directly to veterinarians or other persons allowed to supply such veterinary medicinal products during sponsored events or by sales representatives during their visits, cf. article 119(10) of the Veterinary Medicinal Products Regulation.

The provision implies that samples of veterinary medicinal products cannot be distributed for promotional purposes to the public but only to veterinarians or other persons qualified to distribute such veterinary medicinal products.

11. Enquiries, complaints and legal recourse

11.1. Questions and complaints about advertising

Questions and about the rules on medicinal product advertising and complaints about advertisements should be sent to the Danish Medicines Agency, Axel Heides Gade 1, 2300 Copenhagen S, Denmark, dkma@dkma.dk, see, however, section 10.2 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 Medicines Agency about advertising of medicines can be referred to the Danish Ministry of Health, Holbergsgade 6, 1057 Copenhagen K, Denmark, sum@sum.dk.

11.2. Complaints about advertisements on radio and TV as well as via on-demand audiovisual media services

Complaints about medicines advertisements on the radio and TV as well as via on-demand audiovisual media services [2]should be sent to the Radio and Television Board, Agency for Culture and Palaces, Hammerichsgade 14, 1611 Copenhagen V, Denmark, post@slks.dk.

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

12. Self-regulatory bodies

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

The supervisory activities of the Danish Medicines Agency involving advertising of veterinary medicinal products are supplemented by trade specific self-regulatory bodies that monitor the legitimacy of advertising activities in parallel and collaborate with the Danish Medicines Agency.

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 Medicines Agency. When the Danish Medicines Agency 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 Medicines Agency. But a discontented complainant is not prevented from referring a case to the Danish Medicines Agency, 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 Medicines Agency's review of the case.

12.2. ViNordic Marketing Board Denmark

ViNordic Marketing Board Denmark reviews cases about advertising activities involving veterinary medicinal products pursuant to the Board’s statutes.

Pursuant to the Marketing Board's statutes, the Board reviews and considers complaints in writing from:

– Members of ViNordic and other companies having joined ViNordic's industry-specific self-regulation scheme.

– Others prescribing, distributing by wholesale or retail, using or dispensing registered, veterinary medicinal products in Denmark.

– The Danish Medicines Agency

Complaints can be filed about marketing activities in Denmark involving registered veterinary medicinal products conducted by companies comprised by ViNordic's self-regulation scheme.

In addition, the Marketing Board assesses complaints filed by companies covered by the self-regulation scheme about advertising activities initiated by veterinary pharmaceutical companies outside the self-regulation scheme, with a view to submitting such complaints to the Danish Medicines Agency.

The Board also assesses requests from companies covered by ViNordic's self-regulation scheme for the preliminary approval of specific claims for use in advertising in Denmark.

12.3. 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, Bredgade 54, 1260 Copenhagen K, Denmark, apotekernaevnet.dk.

13. Previous guideline

Guideline no. 10356 of 29 December 2014 on Advertising, etc. of Medicinal Products is repealed.

Danish Medicines Agency, 20 April 2022

Mette Aaboe Hansen

/ Camilla Riesbeck

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.

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