Bird & Bird

Animal Health Regulation

An international overview regarding advertisement of veterinary medicinal products

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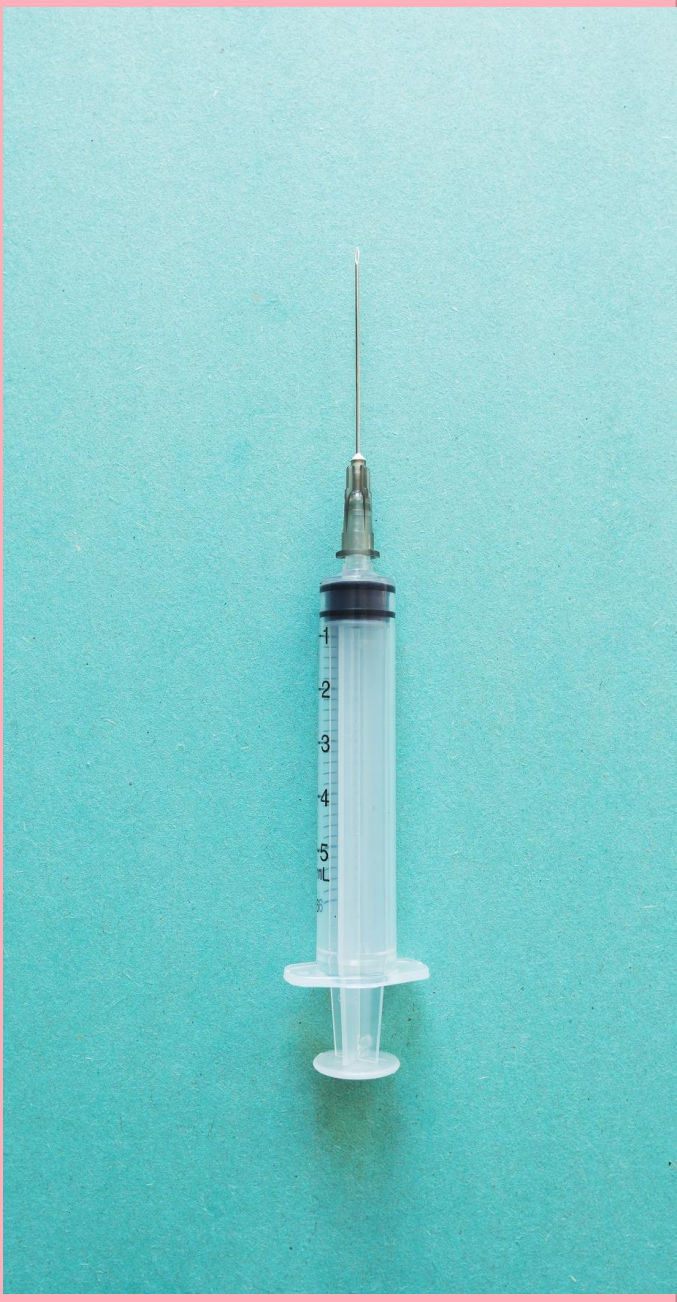

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Introduction

Background

On 28 January 2022, the Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6) (hereinafter: 'VMPR' or 'the Regulation') entered into force and became applicable in all EU countries. The VMPR significantly changed the regulatory landscape with regard to veterinary medicinal products and resulted in harmonisation on several topics – however there is often still some room for national practice. In this document, we specifically focus on the new framework regarding the advertising of veterinary medicinal products, and how it is implemented in six Member States. We further briefly discuss the current legal landscape of the UK from a post-Brexit perspective.

In general, the VMPR creates a specific legal framework for veterinary medicinal products and replaced Directive 2001/82/EC, the previous EU legislation regulating veterinary medicinal products. The VMPR has direct effect and is binding in all Member States. As such, the Regulation automatically forms part of the national legal order. However, some provisions of the VMPR provide (limited) scope for national policy making. Consequently, the VMPR provides a more harmonised regulatory framework. Further detailing of the VMPR will take place in delegated and implementing acts at EU level.

The VMPR contains, amongst others, revised and extended rules on advertising of veterinary medicinal products, thus achieving a certain degree of harmonisation within the European Union. The provisions on advertising are laid down in Art. 119 to 122 VMPR (Chapter VII.4). The aim of these provisions is to ensure that veterinary medicinal products are advertised and promoted in a way that encourages responsible use.[1]

Since advertising of veterinary medicinal products is still not entirely harmonised at European level, the provisions on advertising of veterinary medicinal products may be regulated differently from one Member State to another.

For this purpose, we have provided a regulatory overview for the following countries:

- Belgium
- Denmark
- France
- Germany
- Netherlands
- Poland

This document further contains a chapter on the United Kingdom.

EU Veterinary Medicinal Products Regulation

Before discussing the national practices, we provide some relevant background with regard to the VMPR and advertising in particular. Veterinary medicinal products are defined in the VMPR as *substances or combination of substances intended for use in the diagnosis, treatment, or prevention of diseases in animals, substances aimed are restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, as well as substances used for euthanasia of animals* (Art. 4(1) VMPR). According to the 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* (Art. 4(40) VMPR).

Pursuant to Art. 119(1) VMPR, as a general rule, advertising in a certain Member State is only allowed for veterinary medicinal products authorised or registered in that particular Member State. However, Member States may derogate from this rule. Art. 119 VMPR further prescribes that the promotional nature of the advertising must be clear, the advertising must be in line with the SmPC, must not be misleading, must encourage responsible use, and must be presented objectively. Also, advertising is not permitted

[1] Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6), Consideration (79).

during the suspension of the marketing authorisation.

Regarding the dispensing of samples, the VMPR prescribes that veterinary medicinal products may not be distributed for promotional purposes, except for small quantities of samples (Art. 119(8) VMPR). However, this does not apply to antimicrobial veterinary medicinal products, as antimicrobial veterinary medicinal products may not be distributed for advertising purposes at all (Art. 119(9) VMPR). Samples must be appropriately labelled to indicate that they are samples and must be provided directly to veterinarians or other persons authorised to supply such veterinary medicinal products at sponsored events or by representatives during their visits (Art. 119(10) VMPR). It is up to the national Member States to determine who qualify as persons authorised to supply these products.

Art. 120 VMPR provides rules on the advertising of veterinary medicinal products subject to veterinary prescription. Pursuant to this provision, advertising of prescription products is only allowed when aimed at veterinarians or persons permitted to supply veterinary medicinal products in accordance with national law. In addition, advertising may be permitted by the Member States when aimed at professional keepers of animals (such as farmers) if: i) the advertising is limited to immunological veterinary medicinal products, and ii) the advertising includes an express invitation to the professional keepers of animals to consult the veterinarian about the immunological veterinary medicinal product. Again, the qualification of to which persons advertisement is allowed depends on the practice of the Member States. Furthermore, advertising of autogenous vaccines is always prohibited.

The VMPR also includes some rules on inducement and hospitality. In accordance with Art. 121, no gifts, pecuniary advantages or benefit in kind may be supplied, offered or promised to persons qualified to prescribe or supply medicinal products, unless they are inexpensive and relevant to the practice of prescription or supply of medicinal products. This is based on reciprocity: Persons qualified to prescribe or supply medicinal products shall not solicit or accept any inducement.

This does however not prevent hospitality being offered, directly or indirectly, at events for purely professional and scientific purposes. Such hospitality shall always be strictly limited to the main objectives of the event. As follows from the wording of the article, there is again some room for Member States to provide (for self-regulatory) rules for their own national practice.

Art. 122 VMPR concerns the national implementation of the provisions on advertisement and reads: "*Member States may lay down any procedures they deem necessary for the implementation of Articles 119, 120 and 121*". This again shows that it is important to keep in mind the relevant (possible) differences between the Member States.

United Kingdom

The UK legislation in this area continues to be set out in the Veterinary Medicines Regulations 2013, as amended. It should be noted that the new (EU) VMPR was not implemented in the UK, because it commenced well after Brexit came into effect. It remains to be seen how UK and EU regulation in this area will diverge.

This overview is intended to summarise the national developments and legal frameworks regarding the advertising of veterinary medicinal products in order to assist our clients in understanding their position. This document does not constitute legal advice. If you require more information, please do feel free to reach out to the country contacts in this document. We would be happy to assist you further.

Australia

(1). In which national applicable laws and regulations are the rules with regard to the advertisement of veterinary products laid down? What is the relevant authority overseeing compliance with the VMPR and/or local laws with regard to advertising?

The relevant legislation in this area includes the:

- Agricultural and Veterinary Chemicals Code (Agvet Code);[2] and
- Agricultural and Veterinary Chemicals Code Regulations 1995 (Cth); and
- Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Standard).[3]

The Agvet Code is the legislative framework pursuant to which veterinary chemical products are evaluated, registered and controlled in terms of their manufacture and supply in Australia, including labelling requirements for scheduled poisons. Mirror legislation is found in all States and Territories of Australia.

Additional regulation regarding the supply and handling and labelling of veterinary medicines is found in the Poisons Standard.

The Australian Pesticides and Veterinary Medicines Authority (**APVMA**) is responsible for administering and enforcing the Agvet Code, and it has various enforcement and inspection powers.

Advertising should also comply with the Australian Association of National Advertisers (AANA) Code of Ethics[4] administered by Ad Standards, the body responsible for managing the complaint process of the advertising self-regulation system in Australia.

(2). Under what conditions is advertising of prescription only veterinary medicines allowed and to whom?

Advertising of prescription only veterinary medicines is only permitted in genuine professional or trade journals or other publications intended for circulation only within the veterinary or the wholesale drug industry.

(3). What are the rules on inducement and hospitality in your jurisdiction with regard to veterinary medicinal products?

Accepting an inducement would likely constitute unprofessional conduct and breach the relevant code of professional conduct applicable to veterinary practitioners in each State and Territory. For example, in New South Wales, recommending a product that is accompanied by an inducement to the veterinary practitioner falls under the definition of unsatisfactory professional conduct and may lead to disciplinary action being taken against the practitioner.[5] There is a national code of professional conduct administered by the Australian Veterinary Association which requires veterinary practitioners to, amongst others, comply with the law and uphold the integrity of the profession; however, this is not contained in legislation and is only binding on members.

[2] Schedule to Agricultural and Veterinary Chemicals Code Act 1994 (Cth) ('Agvet Code').
[3] Poisons Standard, s 57.
[4] See https://adstandards.com.au/codes-and-cases/Codes.
[5] Veterinary Practice Regulation 2013 (NSW) s 21; Veterinary Practice Act 2003 (NSW) pt 5.

There are no specific rules around hospitality in relation to veterinary medicinal products. Hospitality is generally permitted to the extent that it is not accompanied by an inducement.

(4). Does applicable national law allow for advertising veterinary medicinal products authorized in another country/member state (pursuant to Art. 119(1) VMPR)?

No - only medicines or active constituents that are registered (or in the process of being registered) in Australia are permitted to be advertised.[6]

(5). Are there any other relevant national rules or legislation on the promotion of veterinary medicinal products that should be considered?

The promotion of veterinary medicinal products must also comply with other requirements under the Agvet Code, including that the advertisement must not include:[7]

- any false or misleading information about the product;
- a claim that the APVMA recommends the use of the product, or guarantees or warrants its safety or efficacy;
- an unjustified claim that the product is natural, organic, safe, harmless, non-toxic, non-poisonous, non-injurious or environment-friendly.

Advertisers should also be cognisant of their obligations under the *Competition and Consumer Act 2010* (Cth), in particular the Australian Consumer Law (found in Schedule 2), ie. that any advertising is not misleading and deceptive, or likely to mislead and deceive.

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[6] *Agvet Code* s 88(2).
[7] Ibid s 89.

Belgium

(1). In which national applicable laws and regulations are the rules with regard to the advertisement of veterinary products laid down? What is the relevant authority overseeing compliance with the VMPR and/or local laws with regard to advertising?

Applicable law and regulations:

- Veterinary Medicinal Product Act of 5 May 2022 (VMP Act)

Relevant authorities:

- Minister of Public Health
- Federal Agency of Medicines and Health Products (FAMHP)

(2). Under what conditions is advertising of prescription only veterinary medicines allowed and to whom?

At this moment the VMP Act does not contain specific conditions on advertising of prescription only veterinary medicines, except for one: Veterinary drugs containing psychotropic or narcotic substances shall not be distributed as samples, as referred to in Article 119(8) of the VMPR.
Amendments to the VMP Act are however expected to enter into force in the future. But it is not certain whether additional national rules on prescription only medicinal products will be added.

(3). What are the rules on inducement and hospitality in your jurisdiction with regard to veterinary medicinal products?

At this moment, the VMP Act does not contain specific conditions.
Amendments to the VMP Act are however expected to enter into force in the future.
At this moment, some ideas for amendments are being discussed. For example, it is possible that in the future an amendment to the VMP Act will enter into force that requires manufacturers of veterinary health products to obtain prior approval, called "visa," from the Minister of public health or its delegate before organizing and / or inviting and providing hospitality to HCPs to professional or scientific events that will take place over several consecutive days. To date, no official confirmation of this idea has taken place.

(4). Does applicable national law allow for advertising veterinary medicinal products authorised in another country/member state (pursuant to Art. 119(1) VMPR)?

No not at present.

(5). Are there any other relevant national rules or legislation on the promotion of veterinary medicinal products that should be considered?

At this moment the VMP Act does not contain specific conditions on advertising of veterinary medicinal products, except that veterinary medicinal products containing psychotropic or narcotic substances shall not be distributed as samples. It can be expected that amendments to the VMP Act will enter into force in the future, and there is a draft proposal circulating, however, to date, nothing has been officially confirmed.

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China

(1). In which national applicable laws and regulations are the rules with regard to the advertisement of veterinary products laid down? What is the relevant authority overseeing compliance with the VMPR and/or local laws with regard to advertising?

Applicable law and regulations:

Articles 21 and 46 of **PRC Advertising Law (2021)** stipulate that an advertisement for veterinary medicine shall be subject to the review of Advertisement Review Authority before publication and shall not contain the following content:

1. any assertion or guarantee for efficacy and safety;
2. names or images of medical research institutes, academic institutions, technology promotion institutions, industry associations or professionals and consumers which are used for recommendation or as proof of efficacy;
3. any statement on the rate of efficacy;
4. words, oral assertion or images that are contrary to the safety use specifications; or
5. any other content which is prohibited by laws and administrative regulations.

Article 31 of **Veterinary Medicine Administration Regulation (2020)** provides that the content of an advertisement for veterinary medicine shall be consistent with the information recorded in the package insert.

Veterinary Medicine Advertisement Review and Publication Rules (2020) specifies prohibited content in an advertisement of veterinary medicine.

Relevant authorities:

Advertisement Review Authority: Ministry of Agriculture and Rural Affairs of the PRC is responsible for the oversight of advertisement published on national major media and the provincial-level agriculture and rural affairs administrations are responsible for the oversight of advertisement published on local media.

Advertisement Enforcement Authority: State Administration for Market Regulation and local administration for market regulations are responsible for the enforcement of any contravention to the PRC Advertising Law (2021).

(2). Under what conditions is advertising of prescription only veterinary medicines allowed and to whom?

The position is currently unclear in China.

Article 15 of **PRC Advertising Law (2021)** states that an advertisement for prescription drug may only be published on medical or pharmaceutical journals which have been jointly designated by the National Health Commission and the National Medical Products Administration. However, the National Medical Products Administration is not the regulator of veterinary medicine in China so it is unclear if Article 15 is applicable to veterinary medicines.

Article 6 of **Online Advertising Administration Measures (2023)** prohibits the publication of online advertisement for prescription drugs. A similar provision was included in the Online Advertising Administration Interim Measures (2016) but it is also unclear whether this provision is appliable to veterinary medicines.

Veterinary Medicine Administration Regulation (2020), **Veterinary Prescription Medicine and Non-prescription Medicine Administration Measures (2014)**, and **Veterinary Medicine Advertisement Review and Publication Rules (2020)** do not contain any provision relating to the advertisement of veterinary prescription medicine.

On 12 December 2022, Nanjing Gaochun District Administration for Market Regulation imposed a fine of RMB 50,000 (approx. USD 7,000) on Nanjing Weite Animal Medicine Co., Ltd. ("Weite") for the advertisements of two veterinary prescription medicines on Taobao. The authorities considered that Weite's advertisements were not consistent with the approved content and were published without the

requisite review approval. Therefore, Weite was sanctioned for publishing the unapproved advertisement. The authority did not rely on the prescription drug related provisions in PRC Advertising Law (2021).
It is recommended that clearance from the authorities should be obtained before any proposed publication.

(3). What are the rules on inducement and hospitality in your jurisdiction with regard to veterinary medicinal products?

Practising Veterinarians and Rural Veterinarians Administration Measures (2022) provides the obligations of the veterinarians, for instance, Article 22 states that veterinarians must:-

1. abide by laws, regulations, rules and relevant administrative provisions;
2. carry out animal diagnosis and treatment activities in accordance with the technical operation norms;
3. abide by professional ethics and perform veterinary duties; and
4. care for animals, and publicize animal health knowledge and animal welfare.

Animal Diagnosis and Treatment Institutions Administration Measures (2022) regulates the activities of animal hospitals and clinics, etc.
In 2012, the Chinese Veterinary Medical Association issued **Code of Ethical Conduct for Practising Veterinarians**, in which Article 17 provides that a practising veterinarian shall not accept rebates, commissions or other unjust enrichment from a manufacturer or distributor of medical equipment, instruments, or medicine.
Other anti-bribery legislations such as **PRC Criminal Law (2021)** and **Anti-Unfair Competition Law (2019)** may also be appliable.

(4). Does applicable national law allow for advertising veterinary medicinal products authorized in another country/member state (pursuant to Art. 119(1) VMPR)?

No. Pursuant to Article 3 of **Veterinary Medicine Advertisement Review and Publication Rules (2020)**, advertisements for veterinary medicine which have not been registered in China are prohibited.

(5). Are there any other relevant national rules or legislation on the promotion of veterinary medicinal products that should be considered?

There could be other relevant national rules or legislation in China such as:-
Civil Code (2021); and
Consumer Rights and Interests Protection Law (2014).

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Denmark

(1). In which national applicable laws and regulations are the rules with regard to the advertisement of veterinary products laid down? What is the relevant authority overseeing compliance with the VMPR and/or local laws with regard to advertising?

All of the measures taken in order to supplement the rules of the new EU Veterinary Regulation are based on an amendment of the Danish Medicines Act.

Some of the supplemental rules implemented as part of such measures are contained directly in the Danish Medicines Act, while others are to be found in administrative regulations, which are referred to as ministerial orders, issued by the Minister of Health, as authorized in the act.

As a short cut to understanding the legislative measures taken in Denmark in reaction to the new EU regulation, one should start by taking a look at the changes made to section 3 of the Medicines Act. Prior to the amendment, it followed from section 3.1 that the provisions of the act generally applied to medicines for humans as well as for animals.

With the enactment of the EU Veterinary Regulation, there is no longer room for a general Danish regulation of medicines for animals and section 3.1 was rewritten, so that it now states:

> *"The act comprises medicines for humans, cf. however subsection 5."*

The newly added subsection 5 states that:

> *"The act comprises medicines for animals to extent provided for herein."*

Through the amendment of this central provision, the general regulation of medicines for animals was elegantly cut out of the act, while outlining the principle that aspects of it applies to medicines for animals, when provided for in specific provisions.

As mentioned above, the measures taken in order to supplement the rules of the new EU Veterinary Regulation also includes the issuance of administrative regulations, or ministerial orders, authorized through the various provisions of the Medicines Act made applicable to medicines for animals. The issued ministerial order with regard to advertisement of veterinary products is:

> **Ministerial Order 130 of 25 January 2022 on Advertising etc. for Medicines for Animals ("Advertising Order")**

Finally, the measures taken also includes various guidelines issued by the Danish Medicines Agency ("DKMA") on behalf of the Ministry of Health, which reflect their summary and interpretation of the EU Veterinary Regulation, the Danish Medicines Act and the ministerial orders issues within various fields. The issued guideline in this regard is:

> **Guidelines on Advertising etc. re. Medicines for Animals, issued by the Ministry of Health on 24 April 2022 ("Advertising Guidelines")**

The Advertising Guidelines make reference to VI Nordic's Advertising Board, a complaints board established by the veterinary pharmaceutical industry, which alongside and in coordination with the DKMA monitors the advertising activities of the pharmaceutical companies and handles complaints.

(2). Under what conditions is advertising of prescription only veterinary medicines allowed and to whom?

As it follows from the Veterinary Regulation Article 120, subsection 1, the advertising of veterinary medicinal products that are subject to veterinary prescription shall be allowed only when made exclusively to veterinarians or to persons permitted to supply veterinary medicinal products in accordance with national law. According to Danish law, this entails veterinarians and pharmacies.

Furthermore, Article 120, subsection 2 allows the member states to permit advertising of prescription medicines in the form of vaccines to professional keepers of animals. However, Denmark has not made use of such possibility. In this regard, it is worth mentioning that vaccines for animals are generally considered prescription medicines in Denmark.

(3). What are the rules on inducement and hospitality in your jurisdiction with regard to veterinary medicinal products?

Samples

There are no additional rules in the Advertising Order regarding samples. However, some guidelines are set out in the Advertising Guidelines section 10.

It follows from the Veterinary Regulation Article 119, subsection 8 that samples of medicinal products may not be distributed for advertising purposes, except as samples in small quantities. The guidelines provide that those small quantities equal to 1-2 packs of a marketed medicinal product per year. If the medicinal product is available in several forms or strengths, 1-2 samples (packs) of each form and strength may be supplied. The samples must be in the smallest pack that is marketed.

The guidelines further state that samples distributed for promotional purposes shall be appropriately labelled to indicate that they are samples and shall be given directly to veterinarians or other persons authorised to distribute such veterinary medicinal products at sponsored events or by sales representatives in the course of their visits.

Lastly, samples of veterinary medicinal products cannot be distributed to the general public for advertising purposes, but only to veterinarians and other persons authorised to distribute such veterinary medicinal products

Gifts

There are no additional rules in the Advertising Order regarding gifts. However, some guidelines are set out in the Advertising Guidelines section 6.

It follows from the Veterinary Regulation Article 121, subsection 1 that when medicinal products are promoted to persons authorised to prescribe or supply them in accordance with this Regulation, no gifts, financial advantages or benefits may be given, offered or promised to such persons unless they are inexpensive and relevant to the person's practice of prescribing or supplying medicinal products.

According to the guidelines, the term 'inexpensive' refers to gifts and benefits of negligible value and the term 'relevant to the person's practice' refers to a gift or other benefit that can be used in the recipient's profession. Thus, both conditions (cheap and relevant) must be met in order to be allowed to give or offer a gift or benefit. An example of a benefit may be the loan of equipment that can be used in the practice of veterinary medicine.

The Regulation does not set a detailed limit on the value of such gifts/benefits, but the guidelines set out that if total value from a giver to the individual authorised to prescribe or supply medicinal products to animals does not exceed DKK 300 in a calendar year, the gift/benefit is in accordance with the Regulation.

The value is not calculated on the basis of what the gift giver - who may be able to obtain significant discounts due to large purchases - paid for the gift, but on the basis of what the recipient would have given for a similar item if he/she had acquired it the usual way. In other words, it is the market value that is taken into account.

Sponsoring

It follows from the Advertising Order section 6, that healthcare professionals must notify the DKMA when they receive payment for the services referred to in the Veterinary Regulation Article 121, subsection 3 in connection with participation in a professional activity abroad or in an international and relevant conference in Denmark.

Further, it follows from the Advertising Guidelines section 6, subsection 3, that the above section in the Order does not cover events organised in connection with the advertising of medicinal products. It only covers "events with a purely professional or scientific purpose".

(4). Does applicable national law allow for advertising veterinary medicinal products authorized in another country/member state (pursuant to Art. 119(1) VMPR)?

No. Denmark has not made use of the possibility.

(5). Are there any other relevant national rules or legislation on the promotion of veterinary medicinal products that should be considered?

There are extensive rules set out regarding advertising veterinary products in a pharmacy in the Advertising Order section 3 and in the Advertising Guidelines section 6, subsection 2.
According to these rules, a pharmaceutical company may pay for advertising space provided by a pharmacy. This inter alia includes payment for renting window space for advertising in a pharmacy, advertising on a monitor in the pharmacy, advertising in pharmacy newspapers, etc.
Payment for the advertising space provided by a pharmacy may not exceed the market price for equivalent advertising space, and the payment may not be dependent on the pharmacy's turnover of the medicinal product. Furthermore, payment may be made only in the form of direct payment, not by any other indirect means, as it follows from the Order section 3, subsection 2. The rules also apply to payment for advertising space provided by a shop selling over-the-counter medicinal products not subject to a pharmacy prescription.
Lastly, there are extensive rules set out regarding discounts on veterinary products in the Advertising Order section 13 and 14 and in the Advertising Guidelines section 7.
It follows from the Order section 13, subsection 1 and 2, that discounts on veterinary medicinal products are lawful if the discount is based on cost savings by the supplier and is a direct consequence of a purchasing behaviour of the recipient that deviates from the supplier's standard terms and conditions (cost-justified discounts) and if the discount shall be proportionate to the cost saving. The section further stipulates, that the supplier shall apply the same principles for calculating discounts to recipients who engage in the same purchasing behaviour.
It follows from the Order section 14, that discounts based on cost savings may only be granted in the form of a reduction in the retailer's purchase price. The discount must be available to the purchaser of the medicinal product and must be clearly related to the supply of the individual medicinal product or batch of medicinal products.

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France

(1). In which national applicable laws and regulations are the rules with regard to the advertisement of veterinary products laid down? What is the relevant authority overseeing compliance with the VMPR and/or local laws with regard to advertising?

Applicable law and regulations

The provisions relating to the advertising of veterinary medicinal products are provided in the French public health code (PHC). French regulation on the advertising of veterinary medicinal products is mainly provided by Decree n°2015-647 of 10 June 2015 on the advertising of veterinary medicinal products (Articles R. 5141-82 and seq. of the PHC) and Decree No. 2017-89 of 26 January 2017 on the transparency of benefits granted by companies producing or marketing veterinary medicines (Articles R. 1453-10 and seq. of the PHC).

Moreover, a guide to good advertising practice for veterinary medicinal products drafted by the French Agency for Food, Environmental and Occupational Health & Safety (*l'Agence nationale de sécurité sanitaire, de l'alimentation, de l'environnement et du travail* – "ANSES") provides rules and recommendations relating to the advertising of veterinary medicinal products.

Relevant authority

The ANSES is designated as the competent authority overseeing compliance of veterinary products advertising with the applicable regulation (Article L. 5141-1 of the PHC). More specifically, within the ANSES, it is the French Agency for Veterinary Medicinal Products (*L'Agence Nationale du Médicament Vétérinaire* – "ANMV") is competent for veterinary medicines in France. It is responsible for:

- monitoring the advertising of veterinary medicines;
- verifying that the advertisements are compliant and contain the information defined by the Regulation;
- examining the consistency between the advertising message and the summary of product characteristics;
- controlling the bibliographic references documenting the claims contained in the advertising.

All advertising documents must be either submitted to the agency (declaration) or approved (authorisation) (depending on the veterinary medicine and public targeted) prior to their distribution.

(2). Under what conditions is advertising of prescription only veterinary medicines allowed and to whom?

Scope of advertising

As a general comment, according to Article R. 5141-82 of the PHC advertising covers any form of information (including canvassing), prospecting or inducement intended to promote the prescription, supply, sale or consumption of veterinary medicinal products. It must be kept in mind that any material bearing a reference, even indirectly, to a veterinary medicinal product might be considered advertising.

- Article R. 5141-82 of the PHC also specifies which documents fall outside of the scope of advertising:
- correspondence, including any non-promotional material, necessary to answer a specific question about a particular veterinary medicinal product;
- sales catalogues and price lists if there is no information on the veterinary medicinal product other than its therapeutic class;
- information documents relating to animal health or animal diseases, provided that there is no reference, even indirect, to a veterinary medicine.

- Advertising is only permitted for authorised veterinary medicinal products (i.e., benefiting from a European or national marketing authorisation or registration (for homeopathic medicines) or parallel import authorisation).

Therefore, medicinal products that are not subject to marketing authorisations, such as auto-vaccines, or products authorised under derogatory access schemes (ATU) cannot be advertised.

Authorised recipient of the advertising

Advertising of prescription only veterinary medicines (in application of Article L. 5143-5 of the PHC**) is allowed only toward persons entitled to deliver them under Articles L. 5143-2 and L. 5143-6 of the PHC, for those they are authorised to prescribe or supply.** They will be referred to as "entitled persons" in the following questions (Article R. 5141-83 of the PHC).

Advertising to the public (including livestock professionals) for medicines not subject to prescription is prohibited (Article R. 5141-84 of the PHC).

- Requirements for advertising prescription only veterinary products

Advertising to professionals and legal persons authorised to supply and prescribe veterinary medicines must contain the following information (Article R. 5141-85 of the PHC):

- The name of the medicinal product;
- The species targeted;
- The qualitative and quantitative composition of the active ingredients;
- The rules governing the prescription and supply of the medicinal product;
- The therapeutic indications, contra-indications and side-effects included in or annexed to the marketing authorisation or registration decision; "
- Where appropriate, an indication of the waiting time
- The authorisation number when the advertising is subject to prior authorisation by the Director General of the ANSES.

All advertising regarding antibiotics shall contain a message indicating that any prescription of an antibiotic has an impact on bacterial resistance and that it must be justified.

The information contained in such advertisements shall be consistent with the information contained in the summary of product characteristics. Such information must be accurate, up-to-date, verifiable and complete to allow the recipient to form a personal opinion of the therapeutic value of the medicinal product.

All written information shall be perfectly legible by the recipient of the advertisement. Quotations, tables and other illustrations taken from scientific journals or books which are used in advertising shall be faithfully reproduced and the exact source shall be indicated.

The advertising shall not refer to the position taken by an administrative authority or advisory body on a medicinal product in such a way as to alter the meaning or objectivity of that position (article R. 5141-85-1 of the PHC).

(3). What are the rules on inducement and hospitality in your jurisdiction with regard to veterinary medicinal products?

Anti-gifts regulation

Under French law, transfer of value from the veterinary industry to professionals of the sector is highly regulated. Indeed, according to Article L. 5141-13-1 of the PHC, the companies responsible for the manufacture, import, export and wholesale distribution of veterinary medicinal products, and of the manufacture, import and distribution of medicinal products undergoing clinical trials (referred to as "companies" in the following questions) are prohibited to provide any advantage in cash or in kind, granted directly or indirectly – including hospitality, payment for services, gifts to the following persons:

- Pharmacists and veterinarians (mentioned in Article L. 5143-2) ;
- Accredited producer groups (professional agricultural groups and health protection groups) mentioned in Article L. 5143-6;
- medicated feed business operators, as well as associations representing them;
- students intending to become veterinarians or pharmacists, as well as associations representing them.

It is also forbidden for these persons to receive such benefits.
However, the prohibition does not apply to:

- benefits provided for in agreements between veterinarians and pharmacists and the veterinary pharmaceutical companies mentioned above, provided that the explicit object and purpose of these agreements is research or scientific evaluation and that such agreements are submitted to the competent professional body prior to their implementation;
- benefits provided for by agreements between students intending to pursue the professions of veterinarians and pharmacists and veterinary pharmaceutical companies when the purpose of these agreements is research activities that are part of the preparation of a degree.
- hospitality offered, directly or indirectly, during promotional events or during events of an exclusively professional and scientific nature when it is provided for by an agreement between veterinarians/pharmacists or students and veterinary pharmaceutical companies and submitted to the competent professional order before its implementation. The hospitality offered must be of a reasonable level, strictly limited to the main professional and scientific purpose of the agreement and is not extended to persons other than the professional concerned.

Rules regarding hospitality and benefits are determined by Decree No. 2017-89 of 26 January 2017 on the transparency of benefits granted by companies producing or marketing veterinary medicines.

Benefits and free samples

The companies are prohibited from directly or indirectly providing users and persons authorised to prescribe or deliver medicinal products with premiums, objects or products of any kind, or from granting direct or indirect material advantages other than the tariff conditions in force.
However, donations intended to encourage research and teaching for the benefit of public establishments or foundations recognised as being of public interest are authorised, subject to prior declaration to the prefect of the department in which these institutions have their headquarters (Article R. 5141-87).
Where veterinary medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are of negligible value and relevant to the prescription or supply of such products.
Regarding free samples, Article R. 5141-88 specifies that the offer of samples is permitted only during the first 2 years following the actual marketing in France or after a significant change in the marketing authorisation (new pharmaceutical form, extension of indication).
Free samples of veterinary medicinal products may only be provided to veterinarians after their written request.

The provision of free samples shall also comply with the following conditions:

- For each medicinal product, only a limited number of samples may be given per year and per recipient, determined according to the nature of the medicinal product and the need for the prescriber to become familiar with it; each sample is identical to the smallest packaging on the market;
- The direct distribution of samples to the public, including to owners or professional holders of animals of species whose products are intended for human consumption, for promotional purposes, as well as their distribution in areas accessible to the public during veterinary or pharmaceutical congresses is prohibited;
- The samples must be identical to the pharmaceutical specialities concerned and the terms: "free sample" must be displayed;
- These samples may not contain antibiotics or substances classified as psychotropic or narcotic, or to which the narcotic regulations are applied.

Regarding, items of negligeable value, they are allowed provided that they relate to the practice of veterinary medicine and/or officinal activities.
These objects may only bear the name or logo of the veterinary pharmaceutical company and/or an institutional message. As an indication, the following objects/supports are allowed:

- pens, pencils, notepads handed out at congresses or trade fairs for the benefit of entitled persons, livestock professionals and the public;
- pencils or any other marking tool not specific to a medicine, given to livestock professionals;

  pockets and briefcases with notepads given to entitled persons at conferences or events reserved for them.

Disclosure and transparency regulation

According to Article L.1453-2 of the PHC, the companies producing or marketing veterinary medicinal products or providing services associated with these products are required to make public the existence of the agreements they have concluded with :

1. Pharmacists and veterinarians (mentioned in Article L. 5143-2) and accredited producer groups (professional agricultural groups and health protection groups) (mentioned in Article L. 5143-6), as well as the associations representing them;
2. Students intending to become veterinarians or pharmacists, and the associations representing them;
3. Higher education establishments for veterinarians;
4. Higher education establishments for pharmacists;
5. Academies, foundations, learned societies and consulting companies or organisations involved in the sector of veterinary medicines;
6. Press publishing companies, radio or television service publishers and publishers of online public communication services;
7. Legal entities other than those mentioned in 3° and 4° providing initial or continuing training for the professionals and groups mentioned in 1° and 2° or participating in such training;
8. Publishers of software to assist in the prescription and delivery of medicinal products.

Companies are also required to make public the advantages offered to natural or legal persons listed above where the amount of each benefit is greater than or equal to €10 including tax (Article D. 1453-1 of the PHC).
According to Article R. 1453-10, companies producing or marketing veterinary medicinal products or providing services associated with these products shall make public the information listed in Article R. 1453-11, in particular:

- The information regarding the agreements concluded with professionals (veterinarians and pharmacists);
- The remuneration paid in the context of the agreements concluded with such beneficiaries;
- The benefits provided directly or indirectly to such beneficiaries, including in the context of agreements.

The information disclosed is made public on the single public website transparence.sante.gouv.fr under the conditions set out in Articles R. 1453-5 to R. 1453-7.
In the context of sale of veterinary medicinal products containing one or more antibiotic substances, discounts, rebates, refunds, differentiation of general and special sales conditions or the provision of free units and all equivalent practices are prohibited. Any commercial practice aimed at circumventing, directly or indirectly, this prohibition by granting discounts, rebates or refunds on another range of products linked to the purchase of these medicinal products is prohibited (Article L. 5141-14-2).

(4). Does applicable national law allow for advertising veterinary medicinal products authorized in another country/member state (pursuant to Art. 119(1) VMPR)?

Under French law, there is no provision allowing advertising of veterinary medicinal products authorised in another country/member state.
According to Article R. 5141-82-1 of the PHC, veterinary medicinal products that may be advertised are the ones that have been:

- granted a marketing authorisation (European or national – French);
- registered before the Director General of the ANSES (registration procedure for homeopathic veterinary medicines);
- granted an import authorisation issued by the Director General of the ANSES.

This could be further updated in consideration of the entry into force of the VMPR, as this Article refers to former Articles that have been abrogated by the Ordinance n° 2022-414 of 23 March 2022 implementing the VMPR and adapting the provisions of the public health code.

(5). Are there any other relevant national rules or legislation on the promotion of veterinary medicinal products that should be considered?

Requirements regarding the person carrying out advertising activities

Advertising for veterinary medicinal products may only be carried out by the holder of the marketing authorisation (MA) for the medicinal products concerned by the advertising or by the person declared by the MA holder to the Director General of the ANSES (Article L. 5142-1-5).

Canvassing or prospection for veterinary medicinal products

Persons who provide information by canvassing or prospection for veterinary medicinal products are required to meet the conditions of qualification defined by decree n° 2016-624, which guarantee that they have sufficient scientific knowledge. They shall report to the veterinary pharmaceutical company all information relating to the use of the veterinary medicinal products they advertise, in particular any adverse reactions brought to their attention by the persons visited. (Article L. 5142-6-1).

Authorisation / declaration procedures

Two types of advertising documents are to be distinguished:

- Those subject to prior authorisation;
- Those subject to prior declaration.

According to Article R. 5141-86, advertising aimed at entitled persons is subject to authorisation:

- when veterinary medicinal products contain antibiotics or substances with anabolic, anticatabolic or beta-agonist activity;

- when veterinary medicinal products are subject to a risk management plan; or
- when they are indicated for use against first category health hazards.

All advertising to the public is subject to prior authorisation regardless of the nature of the veterinary medicinal product.
All advertising materials must be submitted to the Anses-ANMV for declaration or authorisation, at least two months prior to their dissemination. Applications for authorisation and for declaration must be made two months before they are broadcast.
The advertising authorisation delivered by the ANMV shall be valid for two years.
The fees for authorisation / declaration procedures are set out in Article D. 5141-88-1 of the PHC.

Requirements regarding the content of all advertising

Advertising must not be misleading or undermine the protection of human or animal health. It must present the medicinal product in an objective manner and promote its proper use. It should never make veterinary consultation appear unnecessary, nor should it be accompanied by promises or advantages of any kind, nor use certificates/acknowledgments or expert opinions such as testimonies or attestations with a scientific or professional connotation (Article R. 5141-84-1).

Requirements regarding advertising to the public

According to Article R. 5141-85-2, advertising of veterinary medicinal products to the public (provided they are not subject to prescription) must be designed so that the advertising nature of the message is obvious and the product is clearly identified as a veterinary medicinal product;
Besides, the advertising must contain at least:

- The name of the veterinary medicine;
- Information essential for the proper use of the veterinary medicinal product;
- An express invitation to read carefully the instructions on the package leaflet or outer packaging,
- Where appropriate, precautions to be taken by the person administering the medicinal product;
- The statement: "This product is a veterinary medicinal product", accompanied by a message of caution, a referral to the advice of a pharmacist or a veterinarian and, if the symptoms persist, an invitation to consult a veterinarian;
- The authorisation number.

Advertising on the Internet

Websites may be used by veterinary medicinal product companies as a means of communication in compliance with the provisions of the PHC regarding advertising of veterinary medicinal products.
When such sites contain information on veterinary medicinal products, they are subject to the regulations on advertising for veterinary medicinal products and are under the control of the Anses-ANMV. The content of these websites is therefore subject to the submission of the advertising project to the Anses-ANMV and may, if necessary, be subject to prior authorisation. Each company creating a website must inform the Anses-ANMV and provide access to its various pages.
Publicly available promotional messages may only relate to non-prescription veterinary medicines.
For the entitled persons, access restrictions must be put in place by the companies. The provision of a username and a password, after having verified the applicant's status as an entitled person, makes it possible to avoid access by unauthorised persons.
The information displayed on the website must also comply with the provisions regarding the content of veterinary medicines advertising.

Prohibited promotional communication

Apart from the cases explicitly provided for by the PHC (prohibition of advertising to the public for medicinal products subject to prescription and compliance with the MA) and according to the guide to good advertising practice for veterinary medicinal products, certain communications are also prohibited:

- Mailing to breeders and animal owners

The practice of preparing advertising documents in the form of mailings for transmission by veterinarians to their clients is not permitted.

- Promotion of services offered by pharmaceutical companies

  Such offers consist of accompanying the veterinarian on farm visits or organising technical meetings or training for farmers (with or without the attending veterinarian) with the aim of promoting medicines.

  Such offers of services are considered as advertising to the public and are prohibited for veterinary medicines subject to prescription. These offers should therefore be avoided when they concern veterinary medicines subject to prescription.

- **Sanctions in case of non-compliance with the rules on advertising of veterinary medicinal products (Articles R. 5145-2 to R. 5145-4 of the PHC)**

When the Director General of the ANSES considers that the advertising is not compliant with the provisions of the PHC, his authorisation can be conditioned on a change in the content of the advertising, the organisation of the advertising campaign, or on a limitation of the recipients targeted by the advertising.
When examining the advertisements submitted, or when it is found that an advertising campaign or the dissemination of an advertisement is not compliant, the ANSES may give formal notice to the MA holder to amend the content of the advertising, to modify the course of the advertising campaign or to limit the recipients of the advertising, within a specified period of time. The interested party is informed of the possibility of submitting her observations within this period and of being heard by the ANSES.
In the event of non-compliance at the end of the indicated period in the formal notice and where the observations presented are not satisfactory, the ANSES may take the following measures:

- The suspension or prohibition of the advertisement;
- The inclusion of warnings and precautions for use in the advertisement or the dissemination of a correction amending the advertisement;
- The withdrawal of the authorisation of the advertising (when the advertising in question presents the medicinal product as favouring the diagnosis, prevention or treatment of diseases classified as category 1 and 2 health hazards according to Article L. 221-1 of the rural and maritime fishing code).

These measures are made public on the ANSES website.
In the event of an emergency, the ANSES may suspend, for a maximum period of three months, the dissemination of an advertisement that is not compliant with the provisions of the PHC.

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Germany

(1). In which national applicable laws and regulations are the rules with regard to the advertisement of veterinary products laid down? What is the relevant authority overseeing compliance with the VMPR and/or local laws with regard to advertising?

Applicable law and regulations:

- Section 33 of the German Veterinary Medicinal Products Act (*Tierarzneimittelgesetz* – ***TAMG***) referring to Art. 119 to 121 VMPR.
- German Act on Advertising of Medicinal Products (*Heilmittelwerbegesetz* – ***HWG***), but only in respect to procedures and treatments (which are not covered by the VMPR), insofar as the advertising claim relates to the detection, elimination or alleviation of diseases, suffering, bodily injuries or pathological complaints in animals, cf. Sec. 1(1) no. 3 HWG.

Relevant authorities:

- Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit BVL)
- Paul-Ehrlich-Institut

(2). Under what conditions is advertising of prescription only veterinary medicines allowed and to whom?

Art. 120 VMPR

Art. 120(1)(a) and (b): Veterinarians and pharmacies

(As regards medicinal products for use in humans, advertising is also admissible vis-á-vis persons who are allowed to trade in medicinal products [e.g., pharmaceutical wholesalers]. This will likely also apply for veterinary medicinal products. While the German version of the VMPR uses "*abgeben*" (dispense) and appears to be narrower, the English version uses "supply" which would arguably also extend to wholesalers.)

Art. 120(2): Professional keepers of animals*:* The German legislator has not made use of the possibility of allowing advertising to professional keepers of animals.

(3). What are the rules on inducement and hospitality in your jurisdiction with regard to veterinary medicinal products?

Art. 121 VMPR

Hospitality:

- No further provisions apply.

Samples: What are the rules on provision of free samples in your jurisdiction?

- Sec. 46 TAMG: Dispensing of samples
  - (1). Holders of a wholesale distribution permit may dispense a sample of a veterinary medicinal product or a veterinary technical product only to
    - a veterinarian in the smallest package size and no more than two samples each per year; or
    - universities, insofar as the purpose is the education of students of pharmacy and veterinary medicine, to an extent appropriate to the purpose of the education.
  - (2) A sample of a veterinary medicinal product or a veterinary technical product may be provided to persons and institutions of higher education referred to in paragraph 1 only upon a written or electronic request. With the samples, information in accordance with Article 35 VMPR or in

accordance with Section 27 shall be sent, if such information is mandatory. Evidence of the person receiving a sample and of the type, scope, and time of supply of the sample shall be recorded individually for each person. The records according to sentence 2 shall be presented to the competent authority upon request.

- (3) A sample shall not contain any substances or preparations within the meaning of Section 2(1) nos. 1 and 2 of the Narcotics Act listed in Annex II or III of the Narcotics Act.
- (4) Paragraphs 1 to 3 shall apply mutatis mutandis to manufacturers of veterinary medicinal products and veterinary technical products insofar as they hold a manufacturing authorization for the veterinary medicinal product or veterinary technical product concerned.

Further requirements directly follow from Art. 119(10) VMPR whereas, according to Sec. 89(3) no. 25 TAMG, a violation of these requirements can be punished with an administrative fine of up EUR 30,000.

Gifts:

- No further provisions apply.

Sponsoring:

- No further provisions apply.

Under Sec. 89(3) no. 26 TAMG, a violation of the requirements provided for in Art. 121(2) VMPR (i.e., soliciting or accepting any inducement) can be punished with an administrative fine of up EUR 30,000. Further, Secs. 299a and 299b of the German Criminal Code (*Strafgesetzbuch* – ***StGB***) penalize bribery in the healthcare sector. These provisions were, however, not yet adapted to the new legal framework resulting from the entry into force of the VMPR. Thus, it is currently unclear whether they would also apply to veterinary medicinal products.

121(4) VMPR

Under Sec. 53(4) TAMG, the legislator is authorised to enact an ordinance regulating the price margins for veterinary medicinal products. The legislator had not yet made express use of this authorisation. While there is the German Medicinal Products Price Ordinance (*Arzneimittelpreisverordnung* – ***AMPreisV***), this Ordinance was enacted prior to the entry into force of the VMPR and TAMG. It expressly mentions the price margins for products to be supplied to veterinarians and keepers of animals. The AMPreisV was not yet adapted to the new legal framework with veterinary medicinal products being "extracted" from the general regulations for medicinal products for human use. However, according to general principles, the AMPreisV will remain applicable also to veterinary medicinal products until further amendment. Where applicable, further rules on pricing follow from the Veterinarian Fees Ordinance (*Tierärztegebührenordnung* – ***GOT***).

(4). Does applicable national law allow for advertising veterinary medicinal products authorized in another country/member state (pursuant to Art. 119(1) VMPR)?

Art. 119(1) VMPR

No. Germany has not enacted provisions according to which the advertisement of veterinary medicinal products authorized or registered in another Member State is permissible.

(5). Are there any other relevant national rules or legislation on the promotion of veterinary medicinal products that should be considered?

No. Germany has not adopted any further regulations on the promotion of veterinary medicinal products that go beyond the scope of the VMPR. Of course, any advertising of veterinary medicinal products also needs to comply with the general rules for advertising, most notably with the rules of the German Act against Unfair Competition (*Gesetz gegen den unlauteren Wettbewerb* – ***UWG***).

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Netherlands

(1). In which national applicable laws and regulations are the rules with regard to the advertisement of veterinary products laid down? What is the relevant authority overseeing compliance with the VMPR and/or local laws with regard to advertising?

Applicable laws and regulations

As discussed above, as of 28 January 2022, the Veterinary Medicines Regulation concerning veterinary medicinal products is directly applicable in the Netherlands. Furthermore, in the Netherlands, the rules on the advertising of veterinary medicines are regulated in:

1 Art. 8.2 of the Veterinary Medicines Decree 2022 (*Besluit Diergeneesmiddelen 2022); and*

2 The CAVP Code of Conduct (*CAVP Code Aanprijzing Veterinaire Producten*)

Furthermore, in the Netherlands the CAVP Code of Conduct (hereinafter: 'CAVP' or 'the Code')[8] applies, which is a self-regulatory code. The CAVP was drafted by the FIDIN (Dutch Organization for Producers and Importers of Veterinary Medicine, in Dutch: *Fabrikanten Importeurs Diergeneesmiddelen Nederland*) and the KNMvD (Royal Dutch Society for Veterinary Medicine, in Dutch: *Koninklijke Nederlandse Maatschapij voor Diergeneeskunde*) and provides rules and recommendations related to the advertising of veterinary medicinal products. The CAVP's aim is to elaborate the legal provisions in the field of advertising of veterinary products in more detail, to protect professional animal keepers from misleading advertising, and to ensure that advertising complies with the truth and the standards of good taste and decency.

There are many other legal acts which may also apply in a complementary manner to such matters. For example, the rules on misleading advertising in **the Dutch Civil Code** (*Afdeling 4, Titel 3, Boek 6 Burgerlijk Wetboek*) or other (self-regulatory) codes such as **the Dutch Advertising Code** (*De Nederlandse Reclame Code*) are of relevance.

Relevant authorities

In the Netherlands, complaints regarding violations of the CAVP are handled by **the Promotion of Veterinary Products Committee** (in Dutch: *Commissie Aanprijzing Veterinaire Producten,* hereinafter: 'Committee').[9] The Committee, according to the Code, repressively monitors compliance with the CAVP on grounds of received complaints. In principle, all decisions are made public on the website of the Code[10]. It is stated in the Explanation or the Code that when a company fails to comply with the decision, the Committee may submit a complaint against a specific advertisement or action to the **Advertising Code Committee** (in Dutch: *Reclame Code Commissie*) based on the Dutch Advertising Code (in Dutch: *Nederlandse Reclame Code*) or submit the complaint to the **Dutch Food Safety Authority** (in Dutch: *Nederlandse Voedsel- en Warenautoriteit* NVWA).[11] The checks by the Dutch Food Safety Authority are done regularly on a risk base.[12]

[8] An English translation of the Code and well as an explanation to the Code is available on https://www.codeavp.nl/code/code-english.

[9] Art. 2.1 CAVP.

[10] https://www.codeavp.nl/home

[11] Explanation of the Code – Introduction.

[12] See Parliamentary document 2020/21, 35661, 7, p. 9.

(2). Under what conditions is advertising of prescription only veterinary medicines allowed and to whom?

The scope of advertising of veterinary medicines

As a general comment, according to Art. 1.1 of the CAVP the meaning of advertising (also: 'promotion') is '*any public advertising of goods, services or ideas aimed at promoting the supply, sales, prescription, distribution or use of veterinary products*'.[13] In practice, the concept of advertising is broadly interpreted, that is: '*orally, in writing, by means of audio-visual means, through the internet, at exhibitions, conferences and symposia or in any other way*'.[14]

In the Netherlands, the following acts are *not* considered advertising of veterinary medicines (Art. 1.2 CAVP):

- labelling, instruction leaflet and packing of veterinary medicines;
- correspondence, possibly accompanied by material of non-promotional nature, needed to answer a specific question about a particular veterinary product;
- factual, informative announcements and reference material relating to, for example, pack changes, adverse reaction warnings as part of general drugs precautions, trade catalogues and price lists, provided they include no promotional data concerning the veterinary product;
- information relating to animal health and animal diseases, if there is no reference, even indirect, to a veterinary product;
- information on prescription only medicines meant for the public which is not covered by the exceptions set out in Rule 1.2 and which does meet the criteria defined in the Alternative Code of Conduct for providing information on prescription-only medicines, not being promotion[15]

Section 3 of the CAVP provides the general framework for the advertising of veterinary medicinal products. Following this section, advertising may not include misleading or false information and must be recognizable as being a promotion.[16] The advertising must also encourage responsible use and must be presented objectively.[17] Regarding advertising addressed to animal keepers it is additionally stipulated that the promotion may not unnecessarily invoke feelings of fear.[18]

In section 4 of the CAVP special provisions for the advertising of veterinary medicines are laid down.[19] According to Art. 4.1 CAVP promotion of a veterinary medicinal product is only allowed when the product is authorized or registered in the Netherlands.[20] Promotion of veterinary medicinal products during suspension of the authorization in the Netherlands is prohibited.

Furthermore, all claims regarding the performance or other properties of the veterinary medicinal product must be in accordance with the Summary of Product Characteristics (SmPC) and must be presented objectively and stated in a responsible manner (Art. 4.2 CAVP).

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[13] Explanation of the Code – art. 1.1 CAVP.

[14] Art. 1.1 CAVP

[15] Art. 1.2 CAVP

[16] Art. 3.2, 3.3, 3.5 CAVP.

[17] Art. 3.4 CAVP.

[18] Art. 3.6 CAVP.

[19] Please note that section 4 covers promotion of veterinary medicines in general and is not limited to the promotion of prescription-only veterinary medicines. Section 4 in the English translation of the CAVP as published on the website https://www.codeavp.nl/ is erroneously titled "*Extraordinary provisions regarding the promotion of prescription-only veterinary medicines*", while in the original Dutch version of the CAVP section 4 is titled "*Bijzondere bepalingen voor de aanprijzing van diergeneesmiddelen*" which translates to "*Extraordinary provisions regarding the promotion of veterinary medicines*".

[20] Compare art. 119(1) VMPR. In the Netherlands, the government has decided not to make use of the possibility of allowing the advertising of veterinary medicines authorised in another Member State at the moment. See in this regard also question (4).

Also, any citations from or references to scientific works must be representative and variably correct, must be produced with full acknowledgement of the source and must be submitted upon request (Art. 4.3 CAVP).
According to Art. 4.4 CAVP the use of terms, descriptions or images aimed at suggesting the existence of non-existent qualities of products, should be avoided.
Every written form of promotion must contain the following information (Art. 4.5 CAVP):

- Product name and registration number
- Active ingredients
- *At least one indication and target animal**
- *Main side effects and contraindications**
- *Dosage, and, if applicable, withdrawal periods**
- *Most important warnings**
- Classification of the veterinary medicinal product (prescription or not)
- Name and address of the marketing authorisation holder
- Statement that further information is available upon request from the relevant company

* If the promotion is aimed exclusively at reminding people of the veterinary medicinal product and does not contain any other information or claims, this information may be left out (Art. 4.6 CAVP).
Comparative advertising is only allowed if the comparison is not misleading, concerns comparable products, relates to properties relevant to effectiveness and safety, and is not unnecessarily derogatory (Art. 4.7 CAVP). Regarding comparative advertising, relevant rules from the Dutch Civil Code (*Art. 6:194a BW*) also apply.
Also, promotion must not detract from the reputation of and/or confidence in the veterinary pharmaceutical industry or its products, veterinarians and/or animal husbandry (Art. 4.8 CAVP).
Lastly, the promotion may also not be formulated in such a way that the veterinary medicinal product may be confused with being a feed or biocide (Art. 4.9 CAVP).

The scope of advertising of 'prescription only' veterinary medicines

In section 5 of the CAVP special provisions have been included regarding the advertising of 'prescription only' veterinary medicinal products, for which advertising to the public is prohibited by law.[21] In the Netherlands, advertising towards persons who are entitled to prescribe or supply veterinary medicinal products such as veterinarians and pharmacists is permitted under Art. 5.1 CAVP.
However, in the Netherlands the discretion has been exercised to allow veterinary medicinal products to be advertised to professional animal keepers if the conditions laid down in Art. 120, paragraph 2, (a) and (b) VMPR are met (see Art. 8.2 Veterinary Medicines Decree 2022).[22]
The advertising of veterinary medicines requiring a veterinary prescription is only permitted among professional animal keepers if the following conditions are met:

a) The advertising is limited to immunological veterinary medicinal products; and
b) The advertising shall include an express appeal to professional animal keepers to consult the veterinarian about the immunological veterinary medicinal product.

According to the Explanation of the Code, in this context one can think of the promotion of immunological veterinary medicinal products in professional journals, direct mailings or the internet addressed to or during trade fairs and meetings for professional keepers of animals such as farmers.[23] In addition to this, this does not apply to the so-called autogenous vaccines (Art. 120, paragraph 3 VMPR). In case of autogenous vaccines, advertising is *always* prohibited.[24]

[21] See art. 120(1) VMPR.
[22] Compare art. 5.2 CAVP.
[23] Explanation of the Code – art. 5.2 CAVP.
[24] Art. 5.2 CAVP.

Art 5.3 CAVP further prescribes that representatives should have sufficient (scientific) knowledge to provide accurate and complete information about the prescription veterinary medicinal products for which they are making a commendation, and must provide accurate and complete information.

*(3). What are the rules on **inducement** and **hospitality** in your jurisdiction with regard to veterinary medicinal products?*

Following Art. 121 VMPR, the following articles have been included in section 7 of the VMPR with regard to hospitality, gifts and other benefits.
In the CAVP it is mentioned in Art. 7.1 that *'Companies to which the Code applies are: the manufacturers, importers, or traders of veterinary products. Veterinarians and other persons authorized to supply veterinary medicinal products include the following persons: the veterinarian, pharmacist, pharmacist's assistant, veterinary obstetrician, castrator, veterinary assistant, para-veterinary veterinary assistant and license holders insofar as it concerns the marketing of veterinary medicinal products with POM-V status.'*
It is thus important to take into consideration this rather broad scope.

- **Hospitality (Art. 7.1 CAVP)**

According to the CAVP, hospitality in association with gatherings is permitted, if this hospitality is appropriate (within reasonable limits) and strictly limited to the main objective of the gathering. The Code applies to the (direct and indirect) offering of hospitality in association with gatherings with an exclusively professional and scientific character. The gatherings concerned are organised and/or sponsored by companies such as manufacturers, importers, and traders of veterinary products. Depending on the specific meeting, different maximum amounts apply. For scientific meetings, a maximum amount of 500 EUR per event and a maximum of EUR 1500 per year applies. For other events, a lower maximum applies: a maximum amount of EUR 75 per event and a maximum of EUR 357 per year.[25]

- **Benefits (Art. 7.2 CAVP)**

Animal health professionals may accept gifts, pecuniary advantage, or benefit in kind, provided they are inexpensive and relevant to the professional practice. The value of gifts, pecuniary advantages or other benefits received must be modest in size ("low value") and assessed in relation to frequency. The explanation of the Code refers to the concept of "low value" with respect to human medicines. This is estimated at a maximum of EUR 50 per premium or benefit with a maximum of EUR 150 per year per company.[26] It is also included in the Code that this provision does not affect existing measures or trade practices relating to prices, margins and discounts.

- **Samples (Art. 7.3 CAVP)**

In principle veterinary medicinal products may not be distributed for promotional purposes. However, distribution of small quantities of samples, specifically labelled for this purpose is allowed. In the explanation of the Code explicit reference is made to the practice in human medicine, where small quantities are considered to entail two samples per year within a maximum period of two years.[27] This does however not relate to antimicrobial veterinary medicinal products, these may never be distributed for promotional purposes, not as samples, nor in any other presentation.
Samples concern the smallest packaging form of a veterinary medicinal product that, with specific mentioning, are provided free of charge to a veterinarian in order to become acquainted with the veterinary medicinal product in question.

- **Services (Art. 7.4 CAVP)**

Compensation of other services to companies to which the CAVP applies must be reasonable and reflect the fair market value of the services provided. If a service agreement exists, veterinarians and other persons authorised to dispense veterinary medicines shall be entitled to reasonable compensation and

[25] Explanation of the Code – art. 7.1 CAVP.
[26] Explanation of the Code – art. 7.2 CAVP.
[27] Explanation of the Code – art. 7.3 CAVP.

reimbursement of costs actually incurred. Whether a remuneration can be considered reasonable is assessed according to the time spent and whether the hourly rate is market-conform.[28]

- **Sponsorship (Art. 7.5 CAVP)**

Other forms of sponsoring than the provision of hospitality as referred to in Art. 7.1 CAVP by companies directly or indirectly beneficial to members of the animal health professions are only allowed if it is made plausible that the sponsoring involves innovative and/or quality improvement and/or scientific encouraging activities for animal health care and/or charity. The arrangements which cover the sponsoring must be agreed upon in a written contract. Sponsorship usually involves payments for which there is no direct compensation. This must involve sponsoring extra things that benefit innovation, quality or science or support of a good cause.
Financial relationships between veterinary pharmaceutical companies and veterinarians regarding services and sponsorship exceeding the amount of 500 EUR in one year must be reported to the Healthcare Transparency Register Foundation.[29] The Healthcare Transparency Register is publicly accessible.

(4). Does applicable national law allow for advertising veterinary medicinal products authorized in another country/member state (pursuant to Art. 119(1) VMPR)?

According to Art. 119, paragraph 1 VMPR only veterinary medicinal products authorized or registered in a Member State may be advertised in that Member State, unless the competent authority decides otherwise in accordance with applicable national law.
In the Netherlands, the government has decided *not* to make use of the possibility of allowing the advertising of veterinary medicines authorised in another Member State for now:

> "*Finally, a possibility has been added for setting further rules regarding advertising of veterinary medicines. This makes it possible to implement Article 119, first paragraph, second sentence of the Veterinary Medicinal Products Regulation. That provision in the Veterinary Medicinal Products Regulation makes it possible to adopt national legislation on extending the advertising of veterinary medicines authorised in another Member State.* ***It may be desirable to allow this at a later stage if there is a need for it. For example, for veterinary medicines that are not authorised in the Netherlands but are nevertheless essential for certain animal species.*** *As indicated in the transposition table accompanying the explanatory memorandum to the bill, the desirability of making use of this possibility is still being considered*."[30]
> (unofficial English translation)

This also follows from the general rule as laid down in Art. 4.1 CAVP, and advertising is thus only allowed for veterinary medicines that are authorised or registered in the Netherlands.

(5). Are there any other relevant national rules or legislation on the promotion of veterinary medicinal products that should be considered?

Section 6 of the CAVP concerns the codification of Art. 72 of the Biocidal Products Regulation and provides some additional provisions regarding the promotion of **biocidal** products.
Every promotion of biocidal products must comply with the labelling requirements as laid down in Regulation (EC) 1272/2008. Also, the following text must be included in a way that stands out clearly and is legible within the promotion:

> "*Use biocides safely. Before use, read the label and product information*"

The word "biocides" in this text may be replaced by a clear indication of the advertised product type.[31]

[28] Explanation of the Code – art. 7.4 CAVP.
[29] Explanation of the Code – art. 7.6 CAVP.
[30] See Parliamentary document 2020/21, 35661, 7, p. 4.
[31] Art. 6.2 CAVP.

The promotion may not be misleading as to the hazards of the product to human and animal health or the environment or its effectiveness. Promotional statements such as “low-risk biocidal product”, “non-toxic”, “harmless”, “natural”, “environmentally friendly” or “animal friendly” are strictly prohibited.[32]

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[32] Art. 6.3 CAVP.

Poland

(1). In which national applicable laws and regulations are the rules with regard to the advertisement of veterinary products laid down? What is the relevant authority overseeing compliance with the VMPR and/or local laws with regard to advertising?

As of 28 January 2022, Regulation (EU) 2019/6 of the European Parliament and of the Council ("**VMPR**") concerning veterinary medicinal products, is directly applicable. At the same time, the provisions of the Pharmaceutical Law ("**PL**") of 6 August 2001 and the Ministry of Health Regulation of 21 November 2008 on advertising of medicinal products ("**the Ministry of Health Regulation**"), formally continue to apply. However, only to the extent that do not conflict with rules contained in the VMPR.

Although these national regulations (the PL and the Ministry of Health Regulation) will always take precedence in cases concerning advertising of veterinary medicinal products, there are many other legal acts which may also apply in a complementary manner to such matters. Depending on the matter, the provisions of the following acts may be taken into consideration: the Act on Combating Unfair Competition Practices, the Act on Counteracting Unfair Market Practices, the Act on Competition and Consumer Protection, the Act on Radio and Television Broadcasting, the Press Law, the Act on Rendering Electronic Services, the Civil Code and tax regulations, as the questioning of the legality of a given advertisement may result in, i.a. the inability to include the costs incurred for such advertising as tax deductible costs.

On 7 September 2021, the Code of Marketing Ethics (CME) of the Polish Association of Producers and Importers of Veterinary Medicinal Products – POLPROWET came into force, which is a self-regulatory code. POLPROWET's aim is to promote a high standard of ethical behaviour with respect to marketing veterinary medicinal products.

The provisions of applicable national law take precedence over the provisions of self-regulatory initiatives. However, in the absence of precise and exhaustive rules governing the issue in question, such initiatives are of great practical value and can be treated as supplementary to the provisions of Polish law.

The Chief Veterinary Officer (part of the General Veterinary Inspectorate) and the Voivodeship/District Veterinary Inspectorate are responsible for supervising the marketing and use of medicinal products. As part of its supervision, the Chief Veterinary Officer may order:

1. the cessation of the appearance or conduct of advertising of medicinal products contrary to the regulations in force,
2. the publication of the issued decision in the places where the advertising contrary to the regulations in force has appeared, and publication of a correction to the erroneous advertising,
3. removal of the violations found.

In addition, the conditions and methods of advertising are also monitored by the Marketing Ethics Committee of POLPROWET.

The impact of the Chief Veterinary Officer case law on the rules regarding advertising of veterinary medical products is very limited.

The differences in the purpose and intended use of medicinal products for humans and animals also mean that it will not always be possible to apply the interpretation of national regulations on medicinal products advertising developed by the General Pharmaceutical Inspectorate for products intended for humans to the rules regarding the advertising of veterinary products. This is because the specifics of the veterinary sector needs to be taken into account when thinking about the rules developed for the advertising of veterinary medicinal products.

(2). Under what conditions is advertising of prescription only veterinary medicines allowed and to whom?

Recipients of advertising aimed at professionals:

In Poland, prescription only veterinary medicinal products can only be advertised to:

a persons authorized to issue prescriptions (veterinarians) or

b persons trading in medicinal products, which are wholesalers of veterinary medicinal products, the head of the veterinary clinic or a veterinarian designated by the head of the clinic. Wholesalers of veterinary medicinal products perform e.g., activities covering the supply of medicinal products to authorised operators (veterinary clinic, pet shops or other wholesalers).

Advertising medicinal products by providing free of charge samples may only be directed to persons authorized to issue prescriptions. At the same time, this form of advertising cannot involve medicinal products containing narcotics or psychotropic substances.
Polish regulations do not expand the catalogue of persons to whom advertising veterinary medicinal products is possible under Art. 120(2) VMPR.
Conditions for advertising prescription only veterinary medicinal products:
The entity responsible for advertising must assure that the advertising of prescription veterinary medicinal products is not disseminated to the public. This is particularly important regarding online advertising. Advertising a medicinal product to persons authorised to prescribe medicinal products should be presented so as not to reach any unintended recipients.
A medicinal product advertisement should contain information that is consistent with the Summary of Veterinary Medicinal Product Characteristics.
Advertising a medicinal product to persons authorised to prescribe medicinal products must contain the following essential information e.g.: name of the veterinary medicinal product, qualitative and quantitative composition, pharmaceutical form, indication, dosage and method of administration, contra-indications, special warnings and precautions for use, undesired effects, indication of the responsible entity, and the marketing authorisation number.
The documentation provided to persons authorized to issue prescriptions or persons trading in medicinal products should contain information that is reliable, up-to-date, verifiable and complete enough to enable the recipient to make their own assessment of the therapeutic value of the medicinal product, and information on the date of its preparation or last update. Quotations, tables and other illustrations from scientific literature or other scientific works should be faithfully reproduced and include an indication of the source.
Importantly, if prescription veterinary medicinal products advertising concerns a veterinary medicinal product authorized for use in animals whose tissues or products may be intended for human consumption, it should also specify the grace period.
POLPROWET's CME does not specify the catalogue of recipients of prescription veterinary medicinal products advertising. POLPROWET recognizes the need to allow in the future, under the terms of VMPR, advertising of immunological veterinary medicinal products directly to professional animal keepers.

(3). What are the rules on inducement and hospitality in your jurisdiction with regard to veterinary medicinal products?

Medicinal product advertising is understood as an activity that involves informing about or encouraging to use a medicinal product, aimed at increasing the number of prescriptions, supply, sales, or consumption of the medicinal product, and may be based on:

- contacting persons authorised to issue prescriptions or persons trading in medicinal products through sales or medical representatives,
- supplying medicinal product samples,
- sponsoring promotional meetings for persons authorised to issue prescriptions or persons trading in medicinal products,
- sponsoring conferences, meetings, and scientific Conferences or events for persons authorised to issues prescriptions or persons trading in medicinal products.

However, advertising a veterinary medicinal product cannot consist of offering or promising any benefit directly or indirectly in exchange for obtaining a medicinal product or providing evidence that an acquisition has taken place.

Hospitality & Gifts

It is forbidden to direct to persons authorized to issue prescriptions and persons trading in medicinal products advertising of medicinal products consisting in giving, offering and promising material benefits, gifts and various facilities, prizes, excursions, as well as organizing and financing promotional meetings of medicinal products, during which acts of hospitality go beyond the main purpose of the meeting.
Persons authorized to issue prescriptions and persons trading in medicinal products are prohibited to accept the above-mentioned benefits.
The above rules do not apply to giving or receiving gifts valued under PLN 100 related to business practice, bearing a logotype/trade name/trademark of an advertised product or company name.
Breaching the above rules is considered a crime. According to the PL, whoever in the course of advertising a medicinal product, offers or promises material benefits to persons authorized to issue prescriptions or persons trading in medicinal products, or accepts such benefits, will be subject to a fine.

Samples

Supplying free samples is a special type of medicinal product advertising. It can be directed only to persons authorised to issue prescriptions, provided that:

- the person authorised to issue prescriptions has given a written request to the sales or medical representative for supplying the medicinal product samples,
- the person supplying the sample keeps a register of samples supplied,
- each sample supplied is not larger than one medicinal product package of the smallest size authorized for marketing in Poland,
- each sample supplied is marked with the text “free sample – not for sale”,
- each sample supplied is provided together with the Summary of Product Characteristics for veterinary medicinal product,
- the number of samples of the same medicinal product supplied to the same person does not exceed five packages per year.

Providing medicinal product samples to unauthorized persons is a crime, penalized by a fine.
The applicable law and the CME both emphasise the need to implement a system for recording samples provided to veterinarians. Such records of medicinal product samples supplied should include, i.a: data identifying the clinic, name and surname of the person supplying of the medicinal product sample, name and surname of the veterinarian, information regarding the sample itself: name, common name, dosage, quantity, quantity of the medicinal product to be supplied, batch number and shelf life.

(4). Does applicable national law allow for advertising veterinary medicinal products authorized in another country/member state (pursuant to Art. 119(1) VMPR)?

It is recognised by the Polish doctrine that advertising disseminated in one Member State may have cross-border effects and effects in other Member States, especially in the case of online advertising. However, the national Polish regulations do not allow advertising of veterinary medicinal products authorized in another country/ Member State pursuant to Art. 119(1) VMPR. There are currently no plans to allow such advertisement. This is connected with the fact that veterinary medicinal products may only be placed on the Polish market (and thus advertised) after marketing authorisation has been granted in Poland by the competent authority.
According to the PL, advertising of medicinal products not authorized for marketing in Poland is prohibited. Such advertising constitutes a crime, punishable by a fine.
The PL introduces general prohibitions on advertising regardless of its recipients. It is prohibited to advertise medicinal products: which are not authorised for marketing in Poland or are authorised for importation under a target import regime, or which contain information that does not comply with the Characteristic of Veterinary Medicinal Product. The prohibition on advertising also covers medicinal

products that are in the registration process, or at an even earlier stage of marketing, such as clinical trials. For this reason, any announcements regarding new, as yet unregistered products in the portfolio of the responsible entity (e.g., press releases) should not have promotional character that could indicate their advertising nature.
At the same time, it is possible to provide information on ongoing research, clinical trials and registration procedures, provided that they do not assume the character of an advertisement of a specific veterinary medicinal product.

(5). Are there any other relevant national rules or legislation on the promotion of veterinary medicinal products that should be considered?

General provisions

In Poland, advertising veterinary medicinal products may only be conducted by or on behalf of the entity responsible.
The following are not considered as advertising of medicinal products:

1. Information on the packaging of, and accompanying the packaging of, medicinal products which complies with the marketing authorisation,
2. Correspondence accompanied by material of a non-promotional nature necessary to answer questions about a particular medicinal product,
3. Announcements of a non-promotional nature relating in particular to pack changes, adverse-reaction warnings, provided that they do not contain content relating to the characteristics of medicinal products,
4. Trade catalogues or price lists which contain only the generic name, the common name, the dose, the form and the price of the medicinal product,
5. Information relating to animal health or diseases, provided that it does not refer even indirectly to medicinal products.

Whether a given activity constitutes advertising of a medicinal product should be analysed based on a number of factors, e.g., whether the information/press article is financed or co-financed by the entity responsible, as well as the content and form of the information and advertisement perception by the average consumer.

Advertising of OTC veterinary medicinal products

As opposed to the rules regarding advertising of prescription veterinary medicines, advertising of OTC veterinary medicines is allowed to the public, under certain conditions.
Advertising of OTC medicinal products to the public is subject to the following:

1. It cannot be misleading; it should present the medicinal product objectively and inform about its rational use,
2. It cannot suggest the efficacy and safety of the medicinal product or assuring that the use of the medicinal product guarantees the desired effects,
3. It should not contain content suggesting that it is possible to avoid medical advice.

It is also forbidden to advertise an OTC medicinal product if a prescription medicinal product is also marketed under the same trade name.
Veterinary medicinal product advertising directed to the public in the form of audio-visual, visual or audible content should contain a warning with the following wording: "Before use, read the contents of the package leaflet."
Further, it should contain the following data: the name of the medicinal product, the name of the active substance, dosage of active substance, pharmaceutical form, indication or therapeutic indications for use, information on the responsible party.
Medicinal product advertising to the public carried out at the place where the medical or veterinary professional operates may only be displayed in patient waiting rooms.

The CME provides further best practice principles regarding the content of veterinary medicinal products advertising.
According to the CME:

1. The following advertising is unacceptable: a) advertising that is misleading or which leads to the misuse of a veterinary medicinal product, in particular by suggesting that the veterinary medicinal product is a feed or biocidal product, b) covert advertising, understood as a message or action which gives the recipient the impression that it is not advertising but neutral information, (c) advertising which undermines confidence in the veterinary industry.
2. Acceptable advertising: a) conforms to the summary of product characteristics of the veterinary medicinal product, b) is reliable, objective and precise, c) concerns a veterinary medicinal product authorised for marketing in Poland, while it is possible to provide information on ongoing research work, clinical trials and registration procedures, provided that it does not take the form of advertising of a specific veterinary medicinal product.
3. Advertising should encourage the responsible use of the veterinary medicinal product and present the veterinary medicinal product objectively, without exaggerating its properties.
4. Advertising should only use the terms "new" for veterinary medicinal products within one year from their first introduction to marketing in Poland. Use of the terms can also be considered justified in cases of a change of form of the veterinary medicinal product or the addition of a new indication (not yet undisclosed) in the Characteristic of the Veterinary Medicinal Product.
5. Advertising should only use the term "safe" and similar terms in a wider context, justifying the use of these terms.
6. Advertising references in the content of the advertising of scientific data (research results, scientific articles scientific articles, abstracts, charts and graphs) are permitted only provided that:
    a. the scientific data are publicly available, or are part of a registration dossier for a Veterinary Medicinal Product that has been approved by the European Medicines Agency (EMA) or the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products,
    b. they are accompanied by an indication of the author, title and place of publication of the scientific data,
    c. the scientific data have been faithfully quoted, while non-literal quotation (paraphrasing) is permitted, provided that editorial changes do not distort the sense of the scientific data and the overall the tenor of the publication in which the scientific data are included.
7. References to scientific data not publicly available are possible, provided that the member of the Association referring to such data, at the written request of another member of the Association, makes the data referred to in the advertisement available within five working days of delivery of the written request.

Other forms of unlawful advertising

Irrespective of the above-mentioned forms of prohibited advertising, it is also not permitted for unauthorised entities to advertise and offer for sale OTC veterinary medicinal products.
It is very common to advertise OTC veterinary medicinal products by posting information and promotional material about the veterinary medicinal product, as well as the entity's commercial offer on websites or auction and sales portals.
From 28 January 2022, any activity involving mail order sales of OTC veterinary medicinal products without a properly functioning website (and thus advertising placed on such website) will be considered illegal. Entrepreneurs can only conduct mail order sales of OTC veterinary medicinal products dispensed without a doctor's prescription outside veterinary clinics after appropriate notification to the Voivodeship Veterinary Inspectorate competent for the entrepreneur’s place of registered business activity.

Entrepreneurs interested in mail order sales of veterinary medicinal products are required to have a website containing the common logo referred to in Commission Implementing Regulation (EU) 2021/1904 of 29 October 2021 adopting the design of a common logo for the retail of veterinary medicinal products at a distance. They are also obliged to comply with the special requirements for performing business activity involving the sale of medicinal products.
The advertising and sale of a falsified veterinary medicinal products, as defined in Article 2 of Commission Implementing Regulation (EU) 2021/1248 of 29 July 2021 as regards measures on good distribution practice for veterinary medicinal products in accordance with the VMPR, is also prohibited.

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United Kingdom

(1). In which national applicable laws and regulations are the rules with regard to the advertisement of veterinary products laid down? What is the relevant authority overseeing compliance with the VMPR and/or local laws with regard to advertising?

The UK legislation in this area is set out in the *Veterinary Medicines Regulations 2013*, as amended (the "**UK VMR**"). It should be noted that the new EU VMPR was not implemented in the UK, because it commenced after Brexit came into effect. It remains to be seen how UK and EU regulation in this area will diverge.

Compliance with the UK VMR is overseen in the UK by the *Veterinary Medicines Directorate* ("**VMD**"), a government body which also provides guidance to companies on following the regulations and on upcoming changes. Their information hub can be found on their website.[33]

Note that, following Brexit, Northern Ireland ("**NI**") remains subject to EU law under the NI Protocol, though importantly the EU VMPR will not be implemented in NI. The applicable regulations in Great Britain ("**GB**") and Northern Ireland will therefore differ. For example, centrally authorised marketing authorisations will continue to be valid for products which are placed on the market in NI, whereas products placed on the GB market must have a UK marketing authorisation. The supply of veterinary medicines in NI is under review between the UK and the EU to find a long-term solution to the diverging regulatory regimes between the UK and the EU. The grace period was recently extended by three years to 31 December 2025, meaning that veterinary medicines authorised in the UK or placed on the market in GB can continue to be supplied until that date.

Also relevant to the marketing of veterinary medicines is the CAP and BCAP codes, which govern non-broadcast and broadcast advertising respectively (the "**Advertising Codes**"). The Advertising Codes are enforced by the UK Advertising Standards Authority ("**ASA**").

It should be noted that the VMD launched a consultation on the UK VMR on 2 February 2023, proposing changes to modernise the regulations. In particular, the consultation document notes that advertising of veterinary medicines has changed since the UK VMR first came into force in 2013. The consultation ended on 31 March 2023.

(2). Under what conditions is advertising of prescription only veterinary medicines allowed and to whom?

Regulation 11(1) of the UK VMR sets out a general prohibition on advertising veterinary medicinal products which are only available on prescription.

The scope of what constitutes an advert is broad and includes, for example, promotional emails, flyers, online advertising, and text which provides information to the general public about animal illnesses but also promotes a particular medicine as a treatment. Such educational information must not mention products or brand names of prescription medicines, though according to advertising guidance published by the VMD,[34] details of active substances can be included and the informative article can include a strapline setting out the producers of a particular prescription medicine.

There are limited exceptions to this prohibition set out in regulation 11(3) of the UK VMR, which provides the prohibition on advertising prescription medicines does not apply to:

- Price lists (as long as all products are listed with equal prominence); or
- Advertisements aimed at veterinary surgeons, veterinary nurses, pharmacists, or professional keepers of animals.

Presentations to veterinary professionals covering treatment options involving prescription medicines at conferences or training events is permitted

[33] See at https://www.gov.uk/guidance/vmd-information-hub.

[34] Available at https://www.gov.uk/guidance/advertise-veterinary-medicines-legally.

However, advertisement of anti-microbial products to professional keepers of animals is completely prohibited (see regulation 11(5) of the UK VMR).

(3). What are the rules on inducement and hospitality in your jurisdiction with regard to veterinary medicinal products?

Guidance published by the VMD[35] states that medicines must be used for their medical suitability, and not for any financial gain. In particular, the VMD advises that "*suppliers of medicines should not undertake promotions such as discounts or 'buy one get one free' to try to influence prescribers of medicines*."
The UK VMR consultation[36] proposes introducing a regulation setting out the conditions for inducements and hospitality. In broad terms, it would prohibit any gift or inducement being offered unless it is inexpensive and relevant to veterinary practice. Since the proposal is in the consultation phase, it is not yet known whether these new conditions around inducement and hospitality will enter into law, or in what form.

(4). Does applicable national law allow for advertising veterinary medicinal products authorised in another country/member state (pursuant to Art. 119(1) VMPR)?

As mentioned above, Article 119(1) of the EU VMPR does not apply in the UK because the EU VMPR was not implemented into UK law. Therefore, advertising of veterinary medicinal products authorised in another country is not permitted - the products must have a UK marketing authorisation.

(5). Are there any other relevant national rules or legislation on the promotion of veterinary medicinal products that should be considered?

Amongst others, and as briefly mentioned above, the following relevant rules included in the Advertising Codes should be considered:

- the CAP Code, Section 12, *Medicines, medical devices, health-related products and beauty products*
- BCAP Code, Section 11, *Medicines, medical devices, treatments and health*

These sections of the CAP and BCAP Codes cover advertising of medicines, medical devices, treatments, and health-related products (including for veterinary use) in non-broadcast and broadcast media respectively. For example, adverts which involve medical professionals, including veterinary surgeons, and which imply professional advice or recommendation are not permitted
Anyone can refer an advert to the ASA to determine whether it is in compliance with the Advertising Codes, and the ASA regularly publishes rulings on such adverts.

[35] Available at https://www.gov.uk/guidance/advertise-veterinary-medicines-legally.
[36] See at https://consult.defra.gov.uk/vmd/review-of-the-veterinary-medicines-regulations-201/supporting_documents/VMR_2023_Consultation_document_for_VMR_amendments%20version%201.1.pdf.

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Thank you

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