

Conditions regarding the use of the logo for internet trade in veterinary medicinal products

also referred to as

Terms of Use for internet trade in veterinary medicinal products

Veterinary Medicinal Products Unit

Version 3 - 21 March 2024

These Terms of Use are based on Article 104(1) of the <u>Veterinary Medicinal Products</u>

Regulation, which states that persons who may supply veterinary medicinal products in accordance with Article 103(1) must comply with the <u>Veterinary Medicinal Products</u>

Regulation and the applicable legislation of the Member State in which the veterinary medicinal products are sold. These Terms of Use are a summary of a number of important rules that apply to the retail of veterinary medicinal products and in particular to the offering of veterinary medicinal products via internet trade. Retail, including via the internet, is bound by more rules than Article 104(1) of the Regulation and the Terms of Use listed here.

The common logo (hereinafter the logo)

- 1) The Commission <u>Implementing Regulation (EU) 2021/1904</u> establishes the design of a common logo for the retail of veterinary medicinal products at a distance.
- 2) The intellectual property of the logo rests with the European Union.
- 3) The copying or reproduction of the logo for the purposes of representing it as genuine and original is prohibited. You may not make any changes to the logo (the addition of text, symbols, logos or other elements, changes in shape, colour and/or size or any other modification) and it must be displayed on your website exactly as

provided by the Veterinary Medicinal Products Unit. This means that you may not add any text to the logo. This includes the contact details of the Veterinary Medicinal Products unit. The relevant contact details are available via the hyperlink under the logo.

- 4) The logo only contains a link to this web page.
- 5) The logo may only be used on that website that you have registered and which is listed in the Register for internet trade in veterinary medicinal products the Register for internet trade in veterinary medicinal products. The logo may not be used in a context in which it has an advertising effect.
- 6) All veterinary medicinal products that have obtained a marketing authorisation in the Netherlands are listed in the Veterinary Medicines Information Bank. This logo only applies to:
 - Veterinary medicinal products that are listed in <u>the Veterinary Medicines</u>
 Information Bank;
 - Veterinary medicinal products with a <u>marketing authorisation exemption</u> for specific companion animals, such aquarium or pond animals, ornamental fish, cage birds, homing pigeons, terrarium animals, small rodents, ferrets and rabbits;
 - Veterinary medicinal products mentioned on <u>the overview list of veterinary</u> medicinal products that have been scrapped as of 28 January 2022. These veterinary medicinal products, however, are currently still subject to a <u>transitional provision</u>.
- 7) The logo indicates that the veterinary medicinal products above may be sold via your web shop legally. You must therefore display the logo directly on the page where the aforementioned veterinary medicinal product can be placed in the shopping cart by the consumer, to avoid creating the impression that the logo also applies to products other than the veterinary medicinal products above.
- 8) For that reason, displaying the logo on the main page of your web shop is not permitted if you sell products other than veterinary medicinal products.
- 9) After you have registered with the Register for internet trade in veterinary medicinal products, you may immediately display the logo on the relevant page on the website where you offer veterinary medicinal products. The Register for internet trade in veterinary medicinal products is updated once a month. As such, it may be that your registration may not immediately be shown in the Register for internet trade in veterinary medicinal products. In such cases, your proof of registration will be sufficient proof that you are entitled to use the logo, in the event that you are audited for use of the logo. The proof of registration is an automated notification that you will receive immediately after completing the application.
- 10) After you have registered with the Register for internet trade in veterinary medicinal products, you must display the logo on the relevant pages of the website where you offer veterinary medicinal products.
- 11) After you have registered, you may use the logo immediately without notice to the contrary. In the event that an audit of your details shows that you do not comply

- with the requirements for inclusion in the Register for internet trade in veterinary medicinal products, you will be contacted by the Veterinary Medicinal Products Unit, which will request that you remove the logo.
- 12) If your listing in the Register for internet trade in veterinary medicinal products should lapse, you must remove the logo from your website as soon as possible, but within 24 hours.
- 13) As soon as you start offering your veterinary medicinal products via an online platform or app, the rules regarding the use of the logo likewise apply.
- 14) If the use of the logo has previously been prohibited and you have been struck from the Register for internet trade in veterinary medicinal products, you may only reapply for registration in the Register for internet trade in veterinary medicinal products if:
 - if you comply with all the rules regarding the internet trade in veterinary medicinal products at that time and;
 - the reason you were struck from the Register for internet trade in veterinary medicinal products no longer applies.

Registration

15) If you have multiple web shops, you must register each individual web shop separately. If you only have one web shop, but it includes several franchisees, you must register the web shop for each holding. For this you use the address of the head office. The individual franchisees do not need to register separately in addition to this. If you have a web shop that uses multiple domain names, you must register the web shop for each domain name. Please register with the Register for internet trade in veterinary medicinal products here.

Variation

- 16) Any changes to the details and information submitted must be reported immediately. Please report any changes here. The fee for a variation can be found under Fees and product types Veterinary Medicinal Products Unit. Any changes to the information you provided under 'Categories of veterinary medicinal products' do not need to be reported.
- 17) If the information listed in the Register for internet trade in veterinary medicinal products has changed or if you wish to terminate your application for registration in the Register for internet trade in veterinary medicinal products, you must reported this to the Veterinary Medicinal Products Unit immediately by using the change and withdrawal form for internet trade in veterinary medicinal products.

Fees

- 18) The fee for registration with the Register for internet trade in veterinary medicinal products can be found under <u>Fees and product types Veterinary Medicinal Products</u> Unit.
- 19) The fee for a variation can be found under <u>Fees and product types Veterinary</u> <u>Medicinal Products Unit</u>.
- 20) The aforementioned fees will be charged to you as soon as you have submitted your application to us. If it becomes apparent immediately after registration that you do not comply with the requirements for inclusion in the Register or if it appears that your application is incomplete, the aforementioned fees will still be charged. This is because our work will have started at the time you first submitted your application. We therefore recommend that you check your application carefully before submitting it to us.
- 21) You will pay an annual (maintenance) fee for each individual registration.

 The annual fee can be found under Fees and product types Veterinary Medicinal Products Unit. The fee is calculated in the year following that of your registration.

 This means that if you register in 2024, you will be paying an annual fee from 2025. If you wish to withdraw your register listing in the Register for internet trade in veterinary medicinal products, you must do so before the end of the calendar year to avoid having to pay the annual fee of the subsequent year. If you are terminating your registration halfway through the year, you will still have to pay the full annual fee for that year.

Retail of veterinary medicinal products

- 22) Only companies and institutions that are registered with the Dutch Chamber of Commerce can be included in the Register. Foreign companies and institutions can be registered in the country where they are registered.
- 23) If you are supplying veterinary medicinal products online through a non-Dutch language website and are located in the Netherlands, you must likewise register any non-Dutch websites because you are located in the Netherlands. You are similarly required to meet the requirements set out here in respect of non-Dutch language websites. In addition, you must meet the requirements that apply in the country where you are supplying veterinary medicinal products.
- 24) If you hold a D licence, you may only retail veterinary medicinal products of the VRIJ category. These are non-prescription veterinary medicinal products. These veterinary medicinal products may only be sold in another EU Member State if the relevant veterinary medicinal product has a marketing authorisation in the country of destination. You can verify this status in the UPD. You are at all times obliged to check the requirements that apply in the Member States where you supply veterinary medicinal products.
- 25) You may only sell veterinary medicinal products of the URA category if you hold a DR licence. URA stands for 'Only available from a veterinarian or with a veterinary

- prescription from a veterinarian from a pharmacy or a licenced supplier'. You may only offer veterinary medicinal products of the URA category for retail purposes within the Netherlands. If you sell URA veterinary medicinal products, you must provide a description of the URA protocol. This consists of a description of how you ensure that you receive the veterinary prescription, how prescriptions are verified, how they are retained and what information you have listed on your website regarding the use and procedure in respect of the retail of veterinary medicinal products subject to a prescription (you may refer to a relevant web page). You must comply with article 103(3) of the <u>Veterinary Medicinal Products Regulation</u>, which says that you must keep a detailed log of transactions of veterinary medicinal products subject to a prescription.
- 26) You never sell online veterinary medicines of the category 'UDA' or 'UDD' directly to animal owners. Not even if you are a veterinarian or pharmacist. UDA stands for 'Only available from a veterinarian or on veterinary prescription from a veterinarian at a pharmacy' and UDD stands for 'Only for use by veterinarians'. Veterinary medicines in the UDA or UDD category may never be sold online directly to animal owners. Not even if a prescription is requested, if registration or login must take place in advance before the veterinary medicinal product can be ordered or if sales are only made to customers of a veterinary practice. In the Netherlands, Article 4.4 of the Veterinary Medicinal Products Decree 2022 states that retailers with a DR license may offer veterinary medicinal products designated pursuant to Article 5.1, paragraph 2. These concern veterinary medicines of the URA category. This exception does not apply to veterinary medicines of the UDA and UDD categories, which is why they may not be sold online directly to animal owners.
- 27) A veterinarian shall, by operation of law, **only** hold a retail authorisation for the delivery of veterinary medicinal products to animal keepers <u>for those animals for which the veterinarian has undertaken medical care in the course of his profession</u> (Article 4.3(2) of the <u>Decree on veterinary medicinal products 2022</u>). Do you offer veterinary medicinal products of the category VRIJ intended for food-producing animals and/or veterinary medicinal products subject to prescription of the category URA via internet trade and are they intended for animals not covered by your medical care? In that case, you must apply for a D or DR license. You can do this via the form <u>Application for a retail authorisation for veterinary medicinal products</u>. For more information see: 'What rules apply to veterinarians' under the <u>Q&A section</u>.
- 28) If you sell veterinary medicinal products with an <u>exemption for specific companion</u> <u>animals</u> (Article 5.6 of the Veterinary Medicinal Products Regulation), you must ensure that you meet the requirements as outlined <u>here</u>.
- 29) If you sell veterinary medicinal products that are included in the <u>'Overview list of veterinary medicinal products scrapped as of 28 January 2022'</u>, you must ensure that you meet the requirements as set out <u>here</u>.
- 30) Your online retail activities must comply with:
 - a. The <u>Veterinary Medicinal Products Regulation</u> Article 104 Retail of veterinary medicinal products at a distance and
 - b. Commission Implementing Regulation (EU) 2021/1904 and

- c. Section 4.4 of the Veterinary Medicinal Products Decree 2022 and
- d. Electronic commerce legislation, such as <u>Directive (EU) 2015/1535</u> and where applicable the <u>Digital Services Act and Digital Markets Act</u> and
- e. Article 6 of <u>Directive 2000/31/EC</u>
- f. The statutory requirements regarding the <u>advertising of veterinary medicines</u>.
- 31) These Terms of Use are based on Article 104(1) of the <u>Veterinary Medicinal Products</u> <u>Regulation</u>, which states that persons who may supply veterinary medicinal products in accordance with Article 103(1) must comply with the Veterinary Medicinal Products Regulation and the applicable legislation of the Member State in which the veterinary medicinal products are sold. This means that you must comply with all relevant provisions as set out in the <u>Veterinary Medicinal Products Decree 2022</u> and the <u>Veterinary Medicinal Products Regulation 2022</u>.
- 32) The Information that you provide about a veterinary medicinal product with a marketing authorisation must be in accordance with the officially established product text as included in the <u>Veterinary Medicines Information Bank</u>.

Online diagnosis

- 33) The <u>Regulation on Veterinary Medicinal Products</u> (2019/6) Article 105 lays down the following:
 - 3. A veterinary prescription shall be issued only after a clinical examination or other proper assessment of the health status of the animal or group of animals by a veterinarian.

It is therefore not always strictly necessary for a veterinarian to conduct a clinical examination.

The Veterinary Medicinal Products Unit only carries out an administrative check to see whether your website meets the requirements for inclusion in the Register for internet trade in veterinary medicinal products. This administrative check cannot determine whether another proper assessment of the animal's health condition takes place when a veterinary prescription is issued. The NVWA can determine this by means of an inspection.

Moreover for antimicrobials the Dutch law requires company (treatment) agreements between the veterinarian and (professional) animal keepers. The <u>Decree on veterinary medicinal products 2022</u> states, among other things, that a veterinarian carries out regular farm visits (see § 3, Use of antimicrobial veterinary medicinal products by animal keepers).

By means of an inspection, the NVWA can also carry out a verification of compliance with the requirements relating to the company (treatment) agreements.

Making an online diagnosis is not a reason to exclude you from being included in the Register for internet trade in veterinary medicinal products. However, at the moment that an inspection would show that you as a veterinarian do not comply with the

above provisions, the NVWA can, if they see the need to do so, take enforcement actions and/or make a request to the Veterinary Medicinal Products Unit to remove your webshop from the Register for internet trade in veterinary medicinal products.

Transport

34) The storage conditions, such as they have been established for the relevant veterinary medicinal product that you supply, likewise apply during transport. These storage conditions are listed in the product information accompanying the veterinary medicinal product.

Enforcement and monitoring

- 35) The NVWA monitors the online trade in veterinary medicines. This is done in a risk-oriented and knowledge-driven manner. This takes into account the risks to food safety, public health, animal health, animal welfare and the environment. If the NVWA finds violations, enforcement will be carried out. Various sanctioning and corrective interventions can be applied. The NVWA will report violations in the field of internet trade in veterinary medicines to the BD. For more information about supervision or interventions, you can visit the NVWA website: Interventiebeleid | Ondernemers | NVWA, Uitgangspunten NVWA-toezicht | Ondernemers | NVWA.
- 36) If you do not comply with the conditions, Our Minister may take certain measures. Such measures may include you being struck from the Register.
- 37) Your details are shared with the <u>NVWA</u>, given that the NVWA is the control authority in the area of internet trade in veterinary medicinal products.
- 38) If you do not agree with the decision that you will not be included in the Register for internet trade in veterinary medicinal products or in respect of your removal from the Register for internet trade in veterinary medicinal products, you can object within six weeks of the date of notification of the decision by the Veterinary Medicinal Products Unit by:
 - a. submitting a notice of objection to the Netherlands Enterprise Agency, Legal Affairs Department, PO Box 40219, 8004 DE Zwolle, or;
 - b. by visiting the website https://www.rvo.nl/over-ons/juridische-zaken/bezwaar-maken# and submitting your objection electronically.

Your notice of objection should state your correspondence reference number and the date of the email to which you are objecting.

Other

- 39) Your application form for registration should have been completed truthfully.
- 40) You must submit an official Extract from the Chamber of Commerce Trade Register

- alongside your application. Without this Extract, your application cannot be processed, as we use this Extract to verify the authenticity of your application. The fees for the application of this Extract are for your account.
- 41) The Terms of Use set out here remain in force even after any changes to your website. After registration, you must at all times abide by the Terms of Use outlined here.
- 42) Any notifications will be communicated by email.
- 43) We will only contact you at the email address provided regarding the processing of this application and to communicate information regarding the Register for internet trade in veterinary medicinal products.