Newsletter veterinary medicinal products for specific pet animals

According to our information, you as a wholesaler place(d) veterinary medicinal products market in the Netherlands, which are intended for specific pet animals. As may well be known, the regulatory framework for veterinary medicinal products has changed. This is a consequence of the Veterinary Medicinal Products Regulation (EU) 2019/6 (hereinafter: Regulation). This Regulation entered into force on 28 January 2022 and lays down rules on the placing on the market of veterinary medicinal products.

For quite some time there have been non-prescription (or prescription-free) veterinary medicinal products intended for specific pet animals on the market in the Netherlands, with an exemption for the placing on the market of a veterinary medicinal product on the basis of the currently repealed Directive 2001.82.EC (Art. 4.2). The purpose of the exemption is to also have veterinary medicinal products available for less kept and smaller animals. The following were considered to be veterinary medicinal products not subject to prescription in the Netherlands: a. disinfectants, vitamin preparations and corrective preparations; B. Parasites and fungi products intended for non-agricultural animals[1]

What rules apply from 28.1.2022?
For veterinary medicinal products intended for animals which are exclusively kept as pets: aquarium or pond animals, ornamental fish, cage birds, homing pigeons, terrarium animals, small rodents, ferrets and rabbits, an exemption for marketing authorisation may be granted. The condition is that these veterinary medicinal products are not subject to prescription[2]. In the Netherlands, this exemption for veterinary medicinal products can be obtained provided that the European[3] and national requirements are met[4]. Information about the above is also mentioned on the BD website.

What does/does not change with regard to the conditions compared to the 'old' situation? veterinary medicinal product = VMP

Old conditions exemption (RL: Directive 2001.82.EC, NL: national regulations)	**New conditions for exemption (VO: Regulation, NL: national regulations)**
RL: Exemption if no requirement is required for VMP (Policy on prescription of VMP), and;	**VO**: Exemption if no requirement under Art. 34 Regulation is required for VMP. *Conclusion: exemption is retained, but with curtailment (no longer applicable to antimycotics*) *Update of NL Policy on prescription of VMP).*
RL: all measures are taken to avoid improper use of this VMP for other animals. **ENGLISH:** packaging & labelling according to requirements of VMP (Art. 3.7.1.b Veterinary Medicinal Products Regulation).	**VO:** all necessary measures have been taken to prevent the unauthorised use of that VMP for other animals (Art. 2.4. & 5.6) **ENGLISH:** packaging & labelling in accordance with the requirements of Articles 10(1) and (2) 11(1), introductory wording and subsections (a) to (g), (3) and (4), 12, 13 and 14. *Conclusion: content unchanged in NL.*

[1] Article 5 of the Policy Rule on channelisation of veterinary medicinal products
[2] Article 5(6) of the Veterinary Medicinal Products Regulation
[3] Article 2.4 of the Veterinary Medicinal Products Regulation
[4] Article 2.1. of the Veterinary Medicinal Products Regulation 2022

Conditions exemption VMP (RL: Directive 2001.82.EC, NL: national regulations)	**New conditions for exemption VMP (VO: Regulation, NL: national regulations)**
NL: manufacture & import according to GMP requirements (Art. 3.7.1a VMP Regulation)	**VO:** manufacture according to GMP requirements (Art. 2.4. & Art. 94 Regulation). *Conclusion: in NL unchanged.*
NL: the person placing this VMP on the market has a wholesale licence in NL/EU.	**VO**: Distributor (HS: wholesale trade) meets GDP requirements (Art. 2.4 Regulation 99(6) of the NVR). *Conclusion: content unchanged in NL*
NL: Importer, manufacturer, distributor of active substances has been notified in the NL register of NL owners of active substances.	**VO**: Importer, manufacturer, distributor of active substance has been notified to the BD in the (EudraGMDP) API register (Art. 2.1. VMP scheme: comply with Art. 2.2. + art. 95 Vo. 2019/6 — GDP). *Conclusion: content unchanged.*
NL: no requirement notifying exempted VMP and no requirement inclusion in VMP database or register.	**VO:** Notification of veterinary medicinal products by the person placing them on the market. Member State enters data from notified VMP into the VMP database (= UPD) (2.4 Regulation: art. 55 & 56 UPD. *Conclusion: changed. The result: further requirements.*
RL: Article 95a: Collection systems for waste/residue VMP according to national requirements. **NL**: Article 22.1 Environmental Management Act	**VO:** Member State shall ensure an appropriate system for collection of residues and disposal of waste VMP (Art. 117 Regulation). *Conclusion: unaltered.*
RL. Art. 85.3: public advertising for exempted VMP is possible. Prohibition of advertising only for VMP subject to prescription.	**VO:** Article 119.1; advertising possible if VMP is authorised/registered. **ENGLISH:** (5.6. Regulation) only conditions of advertising subject to mandatory VMP. *Conclusion: unaltered.*
RL: Article 84. Supply stop/recall (batches) VMP in case of defects/risks **NL**: Art. 5.15 Animals Act	**VO:** Supply stop/recall (batches) VMP in case of defects/risks (Article 134 Regulation). *Conclusion: unaltered.*
RL: no provision that VMP monitoring requirements apply to exempted VMP.	**VO:** all requirements VMP surveillance (Hfst. Section 5) shall also apply to exempt veterinary medicinal products. *Conclusion: changed.*

Conclusion: many conditions in Art. 2.4. & Art. 5.6. of the Regulation had already been incorporated into NL legislation before 28.1.2022.
New is the obligation to submit an application per veterinary medicinal product and state it after approval in the European Veterinary Medicinal Products Database (UPD) and VMP monitoring requirements.
The status of certain category(s) of veterinary medicinal products of non-prescription (and therefore exempted from a marketing authorisation) has been changed as prescribed (and therefore no longer exempted veterinary medicinal product) on the basis of Article 34 of the Regulation. This is further explained below.
From 28.1.2022, the management of the VET raw materials (API) register has also been invested with the BD (formerly Farmatec) and a notification must be entered in the European database (EudraGMPD) in accordance with Article 95 VO2019/6.

National Elaboration
The European Commission has indicated that Article 5.6. of the Regulation by EU Member States in national regulations need to be further developed.

In order to comply with the requirement for entry in the veterinary medicinal products database (UPD), the Ministry of LNV requested the ACBG, Department of Veterinary Medicinal Products (BD) to set up a hotline for the submission of applications for veterinary medicinal products only for specific pet animals.

On the national elaboration in the Netherlands, the Ministry of LNV decided the following:

1. **Which of the current categories of veterinary medicinal products 'free from prescription' remain subject to Article 34 of the Regulation 'free of prescription' and which VMP are subject to prescription?**

   - As VMP not requiring prior diagnosis by a veterinarian, the following were considered: a. disinfectants, vitamin preparations and corrective preparations; b. antiparasites and fungi intended for non-agricultural animals (Article 5 of the Policy Rule on channelling veterinary medicinal products).
   - The CVMP expert group is working on a guideline for the application of Article 34 of the Regulation (classification of veterinary medicinal products). Further information will follow at the end of 2022.

   - It is already clear that antimicrobials, including *antibiotics, antivirals, antifungal agents and anti-protozoans,* are covered by the prescription requirement. The result: for this category, the exemption expires and a marketing authorisation should also be obtained for a veterinary medicinal product intended for a specific pet animal.

   - The other veterinary medicinal products which are not subject to the prescription requirement may remain on the market provisionally without authorisation, until there is more clarity as to which categories of veterinary medicinal products under Article 34 of Regulation (EU) 2019/6 do not need to be prescribed by the veterinarian.
   - It is expected that an application for a veterinary medicinal product intended for a specific pet animal can be submitted from the beginning of 2023, following the regulatory changes in this area. Further information on the BD website.

   - Please note: For antimicrobials intended exclusively for specific animal species, a transitional period has been agreed:

     - until 28.7.2022 it is still possible to *manufacture* batches;
     - until 31.12.2022 it is still possible for *wholesalers* to supply batches already released to the retail sector.
     - For the retailer and animal holder, delivery/use is possible until the end of the shelf life of the veterinary medicinal product.

     You are requested to check whether there are antimicrobial veterinary medicinal products in your range and, where appropriate, to observe the dates mentioned above.

2. **Does an application for inclusion of an exempt veterinary medicinal product in the veterinary medicinal product database (UPD) also require a dossier of the veterinary medicinal product and to what extent?**
   - It is undesirable if veterinary medicinal products for specific animal species which are not subject to prescription can be placed on the NL market, of which the Dutch government does not know anything. Animal farmers in the Netherlands — even when using a veterinary medicinal product without a marketing authorisation — should be able to assume that the quality, safety and efficacy have been assessed to some extent by the government.
   - Since all requirements of Veterinary Pharmacovigilance must be met, is requires that a shortened dossier be submitted and assessed on the basis of literature.
   - An application can be submitted for one VMP in one Member State, as the requirements are developed nationally.
   - A change in the approved product information, e.g. due to reported adverse reactions is possible.

3. **What information about the veterinary medicinal product (and the applicant) should be provided with an application?**
   - In view of the labelling requirements, it is desirable that an application, in addition to a shortened dossier, be accompanied by a package leaflet.
   - It follows that the following information is requested in the case of an application: product name, qualitative and quantitative composition active and excipients, target animals, manufacturers (active substances, final product and batch release), supplier/wholesale, indication, possibly adverse reactions, administration method, shelf life, pharmacology; efficacy (substantiation incl. limited assessment); package leaflet text containing also information on side effects and pharmacology, packaging text (label and package leaflet); advertising claims (if applicable).
   - If you intend to apply for inclusion of a veterinary medicinal product in the UPD, you as a company must also register with the Organisation Management System. More information about this can be found on our website.

4. **What is the cost of handling an application per veterinary medicinal product?**
   The cost of processing an application is EUR 1 200. The annual costs are EUR 261.

5. **What legal basis in NL is a veterinary medicinal product for which EU Member States can grant an exemption from the marketing authorisation.**
   For each VMP meeting the aforementioned requirements, a 'Special Authorisation' is expected to be issued in NL.