KINGDOM OF BELGIUM

FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS

Royal Decree on the advertising of veterinary medicinal products

PHILIPPE, King of the Belgians,

To all those present and those to come, Greetings.

Having regard to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC;

Having regard to the Law of 5 May 2022 on veterinary medicinal products, Articles 47/1, inserted by the Law of 11 July 2023, 47/2, inserted by the Law of 11 July 2023, 47/3, inserted by the Law of 11 July 2023, 47/4, inserted by the Law of 11 July 2023, 47/5, §1, sixth paragraph, and §2, inserted by the Law of 11 July 2023

Having regard to the Royal Decree of 9 July 1984 on information and advertising of medicinal products;

Having regard to the Royal Decree of 11 July 2003 laying down the conditions under which the supply of medicinal products for veterinary use in the form of samples may be carried out;

Having regard to the notification pursuant to Directive (EU) 2015/1535 to the European Commission and to the EU Member States on XXXX;

Having regard to the opinion of the Finance Inspector, given on 2 January 2024;

Having regard to the agreement of the Secretary of State for the Budget, given on XX XX XXXX;

Having regard to the opinion of the Data Protection Authority, given on XXXXX

Having regard to Opinion No. XX.XXX/XX of the Council of State, given on XX XX XXXX, pursuant to Article 84, §1(1)(1), of the Laws on the Council of State, consolidated on 12 January 1973;
On the proposal of the Minister for Public Health,
WE HAVE DECREED AND HEREBY DECREE:
CHAPTER I. GENERAL PROVISION
Article 1. This Decree supplements and lays down detailed rules for the implementation of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.
CHAPTER 2. ADVERTISING FOR VETERINARY MEDICINAL PRODUCTS SUBJECT TO A VETERINARY PRESCRIPTION
Article 2 This Chapter shall apply to advertising of veterinary medicinal products subject to veterinary prescription intended for veterinary doctors and/or pharmacists.
Article 3 Any person who distributes advertisements for veterinary medicinal products as mentioned in Article 2 shall keep at the disposal of the FAHMP, for five years, a copy of all such advertisements.
For each advertisement as referred to in paragraph 1, a register shall be kept containing the following data:
1. the target audience of the advertisement;
2. the advertising materials and modes of distribution;
3. all the dates when the advertisement was distributed;

4. a file containing all the data and documents that are used to justify or prepare the advertisement.
Article 4 During each visit, the representative of the person who distributes the advertisement shall keep, for each medicinal product he presents, the following documents at the disposal of veterinary doctors and pharmacists and shall hand them to them on request:
1. the summary of product characteristics;
2. the package leaflet and/or labelling, in the case of a homeopathic veterinary medicinal product for which the summary of product characteristics does not exist.
CHAPTER 3. ADVERTISING FOR VETERINARY MEDICINAL PRODUCTS NOT SUBJECT TO A VETERINARY PRESCRIPTION
Section 1 – Advertising for veterinary medicinal products not subject to a veterinary prescription aimed at the general public
Article 5 This Section shall apply to advertising of veterinary medicinal products not subject to a veterinary prescription aimed at persons other than those referred to in Article 2.
Article 6. § 1. Before distributing an advertisement, as referred to in Article 5, for a veterinary medicinal product, a notification to the Minister or to the Minister’s delegate is required.
This notification must be made no later than 30 days before the advertisement is distributed.
§ 2. Anyone who wishes to distribute an advertisement must submit a notification file

to the FAHMP.
The notification file shall contain the following:
1. the advertisement draft;
2. a description of the intended method(s) of distribution;
3. the marketing authorisation number or registration number of the medicinal product and the date of the last marketing authorisation or registration granted;
4. the template of the medicinal product’s packaging.
The notification file shall be submitted electronically using the form that the FAHMP publishes on its website.
§ 3. The FAHMP shall examine the admissibility of the notification file within five working days.
If the FAHMP finds that the notification file is incomplete, it shall inform the notifier thereof within the period referred to in paragraph 1, indicating what data is missing. The notifier has 10 days to complete the file.
If the notification file is not completed within the period referred to in paragraph 2, the notification shall be declared inadmissible. The FAHMP shall inform the notifier thereof in writing.
If the FAHMP finds that the notification file is complete, it shall be declared admissible. The FAHMP shall inform the notifier thereof in writing.
§ 4. Within 30 days of confirmation of the admissibility of the notification file, the FAHMP shall forward any comments on the advertisement to the notifier.
Within 60 days of receipt of the FAHMP’s comments, the notifier may submit an amended advertisement to take due account of the comments.

In the absence of a reply within the time limit referred to in paragraph 2, the notification file shall be closed.
Where an amended advertisement is submitted, the FAHMP shall examine it within 30 days of receipt in accordance with the procedure referred to in paragraph 1.
§ 5. A notified advertisement is valid for two years. This validity begins 30 days after the date of confirmation of the admissibility of the notification file.
The notification shall be renewable.
An advertisement cannot continue to be distributed when the period of validity referred to in paragraph 1 has expired, unless a renewal of the notification has been submitted within the period referred to in paragraph 4.
To renew a notification, a renewal file shall be submitted to the FAHMP no later than 45 days before the end of the validity of the advertisement.
The renewal file shall contain the information referred to in §2 and shall be submitted electronically using the form made available by the FAHMP on its website.
The renewal file shall be processed in accordance with the procedure referred to in paragraphs 3 and 4.
Article 7. Any person who distributes advertisements for veterinary medicinal products referred to in Article 5 shall keep at the disposal of the FAMHP, for five years, a copy of all such advertisements.
For each advertisement, as referred to in paragraph 1, a register shall be kept containing the following data:
1. the target audience of the advertisement;
2. the advertising materials and modes of distribution;

3. all the dates when the advertisement was distributed.
4. a file containing all the data and documents that are used to justify or prepare the advertisement.
Section 2. Advertising of veterinary medicinal products not subject to veterinary prescription intended for veterinary doctors and/or pharmacists
Article 8. Any person who distributes advertisements for veterinary medicinal products not subject to a veterinary prescription aimed specifically at the persons mentioned in Article 2 shall keep at the disposal of the FAHMP, for five years, a copy of all such advertisements.
For each advertisement, as referred to in paragraph 1, a register shall be kept containing the following data:
1. the target audience of the advertisement;
2. the advertising materials and modes of distribution;
3. all the dates when the advertisement was distributed;
4. a file containing all the data and documents that are used to justify or prepare the advertisement.
Article 9. During each visit, the representative of the person who distributes the advertisement shall keep, for each medicinal product he presents, the following documents at the disposal of veterinary doctors and pharmacists and shall hand them to them on request:
1. the summary of product characteristics;
2. the package leaflet and/or labelling, in the case of a homeopathic veterinary medicinal product for which the summary of product characteristics does not exist.

CHAPTER 4. SAMPLES
Article 10. § 1st. This Chapter shall apply to samples of veterinary medicinal products.
§ 2. ‘Sample of a veterinary medicinal product’ means the smallest authorised or registered package on the market of a veterinary medicinal product.
Article 11. §1. The veterinary doctor holding a store of medicinal products who wishes to obtain a sample of a veterinary medicinal product shall request it from the marketing authorisation holder or registration holder or the distributor whom the latter has designated to carry out its advertising activities, by means of a sample order form, in two copies, which must contain at least the following data:
1. the name and surname of the veterinary doctor holding a store of medicinal products and his or her registration number on the list of the Order of Veterinary Doctors;
2. the address of the store, as referred to in Article 5 of the Royal Decree of 21 July 2016 on the conditions of use of medicinal products by veterinary doctors and by persons responsible for animals, and the store number, as referred to in Article 8 of the same Royal Decree of 21 July 2016;
3. the full name, dosage, pharmaceutical form and size of the package included, of the veterinary medicinal product for which a sample is requested;
4. the number of samples requested;
5. the date;
6. the signature of the requestor.
§2. The veterinary doctor holding a store of medicinal products shall keep a complete list per calendar year of the samples requested and received. He/she shall keep this list and have it at the disposal of the FAHMP for five years.
The veterinary doctor holding a store of medicinal products shall ensure the traceability of the samples by keeping a copy of the order form and by completing the entry and exit

records as referred to in Articles 13 and 15 of the Royal Decree of 21 July 2016 on the conditions of use of medicinal products by veterinary doctors and by persons responsible for animals.
§3. The marketing authorisation holder or registration holder of the medicinal product or the distributor designated by it to carry out its advertising activities, who has received an order form as referred to in §1, shall keep it at the disposal of the FAMHP for five years from the date mentioned on the order form.
§4. The marketing authorisation holder or registration holder of the medicinal product or the distributor designated by it to carry out its advertising activities shall have an appropriate control system for the issuing each sample of the medicinal product.
Article 12 The marketing authorisation holder or registration holder of the medicinal product or the wholesale distributor designated by it to carry out its advertising activities shall communicate to FAHMP, in the format established by the latter, by 1 March of each year, the list of samples of each medicinal product which have been handed to each veterinary doctor holding a store of medicinal productsin the previous calendar year.
The list referred to in paragraph 1 shall contain the following data for each veterinary medicinal product and for each veterinary doctor holding a store of medicinal products:
1. the name of the marketing authorisation holder or registration holder of the medicinal product issued in the form of a sample;
2. the complete name of the veterinary medicinal product issued in the form of a sample;
3. the size of the packaging of the sample;
4. the number and lot number(s) of each sample of the medicinal product given to each veterinary doctor holding a store;
5. the store number referred to in Article

8 of the same Royal Decree of 21 July 2016.
CHAPTER 5. INCENTIVES AND BENEFITS
Article 13. The marketing authorisation holder or registration holder of the medicinal product or the distributor designated by it to carry out its advertising activities shall keep a register of incentives and benefits, as referred to in Article 121(1) and (3) of Regulation 2019/6, promised, offered or given to veterinary doctors or pharmacists.
The register referred to in paragraph 1 shall contain the following data:
1. the nature and value of the incentive or benefit;
2. the recipient and/or beneficiary of the incentive or benefit.
That register shall include all the elements necessary to verify compliance with the conditions laid down in Article 121 of Regulation (EU) 2019/6. It shall be kept at the disposal of the FAHMP for five years.
CHAPTER 7. - AMENDING, REPEALING, TRANSITIONAL AND FINAL PROVISIONS
Section 1. Amending provisions
Article 14 The title of the Royal Decree of 23 November 2006 implementing Article 10, §3 of the Law of 25 March 1964 on medicinal products is amended as follows: after the words ‘on medicinal products’, the words ‘and Article 47/5, §1 of the Law of 5 May 2022 on veterinary medicinal products’ are added.
Article 15. In the same Decree, in Article 1, the first sentence is replaced by the following: ‘In order to be approved for the purpose of ensuring the prior authorisation procedure provided for in Article 10, §3(1) of the Law of 25 March 1964 on medicinal products,

hereinafter referred to as ‘the Law’ and as provided for in Article 47/5, §1 of the Law on veterinary medicinal products, hereinafter referred to as ‘the Law on veterinary medicinal products’, the organs provided for in Article 10, §3(5) of the Law on veterinary medicine products and as provided for in Article 47/5, §1 of the Law on veterinary medicinal products must comply with the following conditions:’
Article 16 In the same Decree, Article 1(5) is amended as follows: after the words ‘of the Law’, the words ‘and as referred to in Article 47/5, §1 of the Law on veterinary medicinal products’ are added**.**
Article 17. In the same Decree, Article 2 is amended as follows: in the second sentence after the words ‘of the Law’, the words ‘and pursuant to Article 47/5, §1 of the Law on veterinary medicinal products’ are added.
Section 2. Repealing provisions
Article 18 The Royal Decree of 9 July 1984 on information and advertising of medicinal products is repealed.
Article 19 The Royal Decree of 11 July 2003 laying down the conditions under which the supply of medicinal products for veterinary use in the form of samples may be carried out is repealed.
Section 3. Transitional provisions
Article 20 An advertisement aimed at the general public, already distributed at the time of entry into force of this Decree, must be notified to the FAHMP no later than 3 months after the entry into force of this Decree, as stipulated in Article 21.
Section 4. Entry into force
Article 21 This Decree enters into force on the first day of the third month following its

publication in the Belgian Official Gazette (Moniteur belge).
Section 5. Operative provision
Article 22 The Minister for Public Health shall be responsible for the implementation of this Decree.
……, on ……..
By the King:
The Minister for Public Health,
FRANK VANDENBROUCKE