MINISTERIO
DE SANIDAD, CONSUMO
Y BIENESTAR SOCIAL

agencia española de
medicamentos y
productos sanitarios

CIRCULAR Nº 1 / 2019

ORGANISATION: Spanish Agency of Medicines and Medical Devices (hereinafter AEMPS).

CONTENT: Inclusion of Braille format in specific veterinary medicines.

SCOPE OF APPLICATION: Veterinary Pharmaceutical Industry.

The consolidated text of the Act on guarantees and rational use of medicines and medical devices, approved by the Royal Legislative Decree 1/2015, of 24 July, establishes in its article 31.5 that: "*In order to guarantee access to information for people who are blind or have a sight disablement, the necessary provisions will be developed by regulation so that on the containers of medicinal products intended for companion animals the necessary data for their correct identification are embossed in Braille, as well as the authorisation holder guaranteeing that, prior request of the associations of people affected, the package leaflet is available in appropriate formats for the blind or partially sighted people*".

The AEMPS issues this circular with the aim of regulating the procedure for the inclusion of the correct identification on the containers of the veterinary medicinal products intended for companion animals (including guide dogs) for the blind or partially sighted people.

First. Scope of Application

This circular is aimed at those veterinary medicinal products that have among the target species authorised some that belong to the group of companion animals, regardless of the authorisation procedure that has been followed.

This circular does not apply to the following groups of veterinary medicinal products intended for companion animals:

a) Those medicinal products that may only be administered by veterinarians, in accordance with article 23. 2, a) 1.º of the Royal Decree 1246/2008, of 18 July, by which the procedure of authorisation, registration and pharmacovigilance of the veterinary medicinal products manufactured industrially, is regulated.

b) Immunological veterinary medicinal products.

c) Veterinary medicinal products of parenteral administration.

Second. Minimum information to be included in Braille

The minimum information to be included in Braille shall only be on the outer packaging of the medicinal product and shall be:

a) The particle vet (in lower case) followed by a space should be added at the beginning before the name. This will differentiate them from the medicinal products for human use.

b) The complete name of the veterinary medicinal product (in lower case), in other words: the commercial name (invented name or brand name or Official Spanish Denomination (DOE) / International Non-Proprietary Name (INN) + Brand name or name of the marketing authorisation holder).

c) The pharmaceutical form.

Depending on container size, this information should be included using one or more surfaces of the outer packaging.

Where, due to space, the complete aforementioned information does not fit on the packaging, the AEMPS may authorise the elimination of certain items in the following order: pharmaceutical form and name or trade name of the holder (in the case of generic medicinal products). In order to prove the lack of space, the marketing authorisation holder should present a model with the Braille embossed. These exceptions shall be evaluated and authorised case by case.

When the alphabet Braille identification of multilingual packs can cause confusion or lead to medication misuse, the applicant / marketing authorisation holder may request the AEMPS not include the pharmaceutical form. This exception shall be evaluated and authorised case by case.

Third. Organisation of the procedure and documentation

The applicants of a new marketing authorisation or of a variation of a marketing authorisation of veterinary medicinal products that are affected by this circular should, once the favourable opinion has been obtained from the Committee for Veterinary Medicinal Products of the AEMPS (hereinafter CODEMVET) or the Committee for Veterinary Medicinal Products of the European Medicines Agency (hereinafter CVMP) (according to the procedure) and in accordance with the calendar established in the Fourth paragraph of this circular present the original certificate issued by the company ILUNION Salud, S.A. which certifies that the proposal of identification of the medicinal product in Braille is correct.

Fourth. Period of implementation

The applicants of a new authorisation or of a variation affected by this circular should proceed with the appropriateness of their medicinal products according to the procedure indicated in the Third paragraph and in accordance with the following calendar:

1) Newly registered veterinary medicinal products. This shall apply to all the veterinary medicinal products that obtain the favourable opinion for marketing authorisation of the CODEMVET or of the CVMP (for centralised procedures) as of **1 January of 2020**.

2) Veterinary medicinal products already authorised. This shall apply to all the variations that affect outer packaging and to all the renewals of their marketing authorisation that obtain the favourable opinion of the CODEMVET or of the CVMP as of **1 January of 2020**.

3) All the veterinary medicinal products encompassed by this circular should fulfil the requirement of the incorporation of Braille on the outer packaging before **1 January of 2022**.

Failure to comply with the obligation of correct identification of these veterinary medicinal products in the maximum periods indicated shall lead to the breach of article 31.5 of the consolidated text of the Act on guarantees and rational use of medicines and medical devices, approved by the Royal Legislative Decree 1/2015, of 24 July, which shall result in the immediate initiation of the corresponding procedure of suspension of the marketing authorisation.

Fifth. Date of application.

This circular shall apply as of the date of its publication in the AEMPS web page.

Madrid, 3 December 2019

THE DIRECTOR OF THE SPANISH AGENCY OF MEDICINES AND MEDICAL DEVICES

agencia española de medicamentos y productos sanitarios

Mª Jesús Lamas Díaz

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID