Ministero della Salute

DIREZIONE GENERALE DELLA SANITÁ ANIMALE E
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<Spazio riservato per l'apposizione dell'etichetta di protocollo>

0008359-08/04/2020-DGSAF-MDS-P

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SUBJECT: new procedures for the approval of product information of veterinary medicinal products.

Trade associations and MA holders are informed that, with a view to limiting the spread of the SARS-CoV-2 infection, this Administration has implemented smart work as a regular mode of organization to meet social needs.
In particular, in order to avoid interrupting the administrative activity and the authorization of veterinary medicinal products, which could result in a shortage of medicines on the market, the procedure to collect the documents necessary to correct and approve the final leaflets has been modified as detailed below.

After obtaining new MAs, extensions, major variations and renewals under national or European procedures, MA holders are required to submit the following:
- SPC, package leaflet, inner and outer labels of the products proposed for marketing, in word format;
- a copy of the original inner and outer labels (*mock-ups*) of the smallest package proposed for marketing. The external label mock-up must include an area for the machine-readable code in compliance with the provisions set out in Ministerial Decree of 17 December 2007, as well as an area for the dosage prescribed;
- where the minimum information is included, a copy of the original small inner label (mock-up);

- a copy of the original package leaflet (mock-up), only where it is an integral part of the external packaging (label/package leaflet).

In the event that the mock-ups differ depending on the package, the company must provide one for each package.

Also, it should be noted that the copies of the original internal and external labels submitted in pdf format must have the following characteristics:
- the actual size of the labels must be indicated;
- small labels must be legible and the font type and size must be specified;
- if the actual size is greater than the A4 sheet, the labels must be reduced and the percentage of the reduction to the actual format must be indicated.

When submitting the proposed labeling of medicinal products, companies must comply with the instructions provided by the EMA in document "*Guidance for checking mock-ups*" *(EMA/102667/2014).*
This Office shall provide MA holders and/or the contact point designated in the application form with the afore-mentioned information leaflets, corrected and approved by the people in charge of the procedure, in a non-editable pdf format.

Within **10 working days** from the date of notification, any counterclaims to the corrections made to the information leaflets or their acceptance must be submitted by the company by certified e-mail (PEC) or by regular e-mail.
After receiving the notification of the electronic leaflets and in the absence of counterclaims, the company must send confirmation of acceptance to dgsa@postacert.sanita.it and, for information, to the people in charge of the procedure, whose e-mail addresses can be found in the notification letter. The scanned revenue stamps (*marche da bollo*) must be affixed on the company's letterhead and canceled, and the document must be signed, dated and stamped by the company's legal representative or a delegate. The type of procedure or the number of the authorization procedure (for European procedures), the name of the medicinal product and the MA number must be specified in such document.
A sufficient number of revenue stamps (*marche da bollo*) must be provided to issue the authorization and the attached leaflets, as indicated in the notification letter. The notification letter is attached hereto.

Finally, please note that a further change relates to the procedure for the issue of advertising messages for veterinary medicinal products to be attached to the authorization decree. In particular, after the Office's approval of the advertising message, the company must send the scanned approved advertising message to dgsa@postacert.sanita.it and, for information, to the people in charge of the procedure. Two revenue stamps *(marche da bollo),* one for issuing the decree and one for the advertising message, must be affixed on the first page and canceled.

THE DIRECTOR OF THE OFFICE
**Dr. Angelica Maggio*

**"handwritten signature replaced by printed signature pursuant to Article 3, Paragraph 2 of Legislative Decree No. 39/1993"*