



Ministero della Salute

DIREZIONE GENERALE DELLA SANITÀ ANIMALE E DEL FARMACO  
VETERINARIO

Ufficio 4- Medicinali veterinari  
Viale Giorgio Ribotta, 5 - 00144 Roma  
dgsa@postacert.sanita.it

Ministero della Salute

DGSAF

0002670-P-01/02/2019



To:  
European Commission, Grange, Dunsany C15  
DA39, Co. Meath, Ireland - Office: GRAN  
01/102

[SANTE-IRL-audits@ec.europa.eu](mailto:SANTE-IRL-audits@ec.europa.eu)

SUBJECT: REFERENCE NUMBER: DG(SANTE)/2018-6371 - MR  
FACT-FINDING MISSION IN ITALY FROM 8 TO 16 NOVEMBER 2018 IN ORDER TO GATHER INFORMATION  
ON THE PRUDENT USE OF ANTIMICROBIALS IN ANIMALS

With reference to the subject and with a view to providing a more objective report, the additions to the following points are listed below.

**Point 20.** *Veterinarians are not allowed to sell veterinary medicines in Italy. Farm animal veterinarians can deliver an initial dose of medicine to initiate treatment of the animal. Small animal veterinarians are permitted to supply one full sealed package of medicine to the pet owner.*

It would be desirable to include the following wording referred to in article 84, paragraph 6 of Legislative Decree No. 193/2006 implementing Directive No. 2004/28/EC on the Community code relating to veterinary medicinal products: "Although the conditions provided for in article 10 of the Decree are met, medicinal products for human use to be supplied only to hospitals and nursing homes containing antibacterial agents shall not be supplied to the structures performing veterinary professional activity."

**Point 21.** *Farmers can apply to their local health unit to keep stocks of veterinary medicine products (VMPs) on their farm. An inspector will visit the farm to ensure that there is a lockable cabinet where VMPs will be kept and that a veterinarian to manage them is available. Records need to be kept on the farm of the quantities of VMPs purchased and consumed and such farms are inspected by the local health unit at least once a year.*

It would be desirable to include the following wording referred to in article 81 of Legislative Decree No. 193/2006 implementing Directive No. 2004/28/EC on the Community code relating to veterinary medicinal products: "In the case of facilities for rearing and keeping animals intended for food production authorized to keep stocks of veterinary medicinal products, public bodies or institutions, pharmaceutical companies, wholesalers or feed mills shall not employ veterinarians responsible for storage and use, and not even their assistants."

**Point 22.** *A national law recently approved (167/2017) makes it compulsory for veterinarians to use an electronic prescription system for VMPs from 1 January 2019.*

It would be desirable to replace the above-mentioned wording with the following: “A national law recently approved (167/2017) makes it compulsory for veterinarians to use an electronic prescription system for VMPs from 1 January 2019”. To date, the veterinary electronic prescription is used throughout the national territory but it is still not mandatory pending publication in the Official Journal of the implementing Decree of the Ministry of Health.

**Point 49.** *The VMP wholesaler visited emphasised that the market was very competitive with pharmaceutical companies offering rebates, premiums and other incentives to farmers based on the quantities of products (including antimicrobials) that they buy. Such rebates are paid to the farmer by the wholesaler or retailer selling the product. The existence of promotional advertisements encouraging the use of 3rd and 4th generation cephalosporins such as ceftiofur in cattle to treat metritis and foot rot were also highlighted during the mission.*

It would be desirable to include the following wording referred to in articles 87 and 107 of Legislative Decree No. 193/2006 implementing Directive No. 2004/28/EC on the Community code relating to veterinary medicinal products, as well as in article 1, paragraphs 2 and 3 of Ministerial Decree of 14 June 2002 on the advertising to the general public of medicinal products: “the Italian legislation prohibits the advertising to the general public of veterinary medicinal products subject to veterinary prescription, including those containing substances having an antimicrobial action, except in the case of dissemination of scientific knowledge dedicated just to veterinarians”.

Finally, it is pointed out that the above was notified to competent regional authorities and vet associations with a special communication and it is available in the specific section on antimicrobial resistance of the website of the Ministry of Health in Italian and in English:

<http://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2019&codLeg=67719&parte=2&serie=>

THE DIRECTOR GENERAL  
Dr. Silvio Barello



