



DG Inspection/Dispensing Division/ Medical stocks at Veterinarians Entity

Modification of the veterinary prescriptions and the administration and supply document

Dear Sir or Madam,

On 28 January 2022, the <u>EU Regulation on medicinal products for veterinary use</u> entered into force. Among other things, this implies that veterinarians have the obligation to use a new model format for veterinary prescriptions.

Veterinary prescriptions

The modification of veterinary prescriptions will be carried out in several phases.

Phase 1: from 28 January 2022 onwards

The veterinarian uses one of the two current models and includes the following information.

- 1. For two-part prescriptions (green/blue) that may only be used for non-food-producing animals:
 - the identification of the animal or groups of animals to be treated,
 - the active substances of the medicinal product,
 - the pharmaceutical form and strength,
 - the quantity prescribed or the number of packs and their pack size,
 - any warnings necessary to ensure the proper use including, where relevant, to ensure prudent use of antimicrobials,
 - mention 'cascade' for a medicinal product prescribed under the cascade system,
 - mention 'prophylaxis' or 'metaphylaxis' if it concerns an antimicrobial used for prophylaxis or metaphylaxis.
- 2. For three-part prescriptions (white / yellow / pink):
 - the active substances of the medicinal product,
 - the pharmaceutical form and strength,
 - the quantity prescribed or the number of packs and their pack size,
 - any warnings necessary to ensure the proper use including, where relevant, to ensure prudent use of antimicrobials,
 - mention 'cascade' for a medicinal product prescribed under the cascade system,
 - mention 'prophylaxis' or 'metaphylaxis' if it concerns an antimicrobial used for prophylaxis or metaphylaxis.

Warning

Prescriptions for **antimicrobials** shall be valid for a **maximum of five days**.

For all other medicinal products, prescriptions shall be valid for a maximum of fifteen days if they concern food-producing animals and six months if they concern non-food-producing animals.

What is meant by 'identification of the animal or group of animals'?

What allows for the most reliable distinction between the animal or animals to be treated.

Definition of antimicrobials

Any substance with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including **antibiotics**, **antivirals**, **antifungals** and **antiprotozoals**.

Phase 2: upon publication of the Belgian model (date will be communicated later)

There will be a six-month transition period where the three models will co-exist:

- the new Belgian model,
- the old two-part Belgian model completed as requested in phase 1.
- the old three-part Belgian model completed as requested in phase 1.

Phase 3: at the end of the six-month transition period

Only the new Belgian model is valid.



Phase 4: the European Commission may, by means of implementing acts, set a model format for veterinary prescriptions

Upon publication of the implementing acts, only the European model shall be valid.

Administration and Supply Document (ASD)

The modification of the ASD will take place in several phases.

Phase 1: from 28 January 2022 onwards

The veterinarian uses the current model and includes the following information:

- 1. If the ASD serves to keep record of the medicinal products leaving the veterinarian's depot:
 - the pharmaceutical form and the strength of the medicinal product,
 - the batch number,
 - the marketing authorisation (MA) number,
 - the contact details of the veterinarian who administers or supplies the medicinal products.
- 2. Mention 'cascade' for a medicinal product used under the cascade system.
- 3. Mention 'prophylaxis' or 'metaphylaxis' if it concerns an antimicrobial used for prophylaxis or metaphylaxis.

Phase 2: after publication of the new model of the ASD (date will be communicated later)

There will be a six-month transition period where the two models will co-exist:

- the new model of the ASD,
- the old model of the ASD completed as requested in phase 1.

Phase 3: at the end of the six-month transition period

Only the new model for the ASD shall be valid.

Contact

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