Veterinary Medicines Directorate

In view of the updated Government guidelines in response to the COVID-19 pandemic, this notice has been amended to provide that the VMD has made a final extension to the temporary change to the standard VMD guidance on "Manufacturers of extemporaneous preparations for use under the cascade (ManSA)". This relaxation will now last until 31 August 2020 and then cease.

Extemporaneous products: temporary change of supply

Change of guidance during COVID-19

Guidance for supply of extemporaneous products

This statement concerns the standard Veterinary Medicines Directorate (VMD) Guidance on "Manufacturers of extemporaneous preparations for use under the cascade (ManSA)": https://www.gov.uk/guidance/manufacturing-authorisations-for-veterinary-medicines#manufacturers-of-extemporaneous-preparations-for-use-under-the-cascade-mansa

In particular, the following section of the standard guidance:

You may only supply an extemporaneous product to a veterinary surgeon if all of the following apply:

- *there is a genuine order from a veterinary surgeon registered in the UK;*
- *the product is formulated in accordance with the veterinary surgeon's requirements;*
- *the product is for administration to an animal under the veterinary surgeon's care on their direct personal responsibility.*

The order and distribution of extemporaneous products should be in response to a clinical need in specific animals. This should be a direct process between the prescribing vet and the manufacturer, and they cannot be supplied via a third party such as a wholesale dealer.

During the COVID-19 pandemic

Effective immediately, in view of the unique challenges caused by the COVID-19 pandemic, the VMD will adopt the approach set out below with regard to the supply of extemporaneous products by ManSA holders until 31 August 2020.

In practice, this means that during the current period a supply of extemporaneous product which is made direct to the end user by a third party who is a ManSA holder, is allowed in cases where the following procedures are observed.

- An RCVS-registered prescribing veterinary surgeon must provide a genuine order/prescription to the ManSA holder, for a product intended for administration to an animal under the veterinary surgeon's care and on their direct personal responsibility. The prescribing veterinary surgeon must:
    - in this order provide, in addition to the standard information, the following information to the ManSA holder:

        - the name and address of the veterinary surgery prescribing the veterinary medicinal product;
        - the name of the veterinary surgeon who has prescribed the product;
        - the name and address of the animal owner;
        - the identification (including the species) of the animal or group of animals;
        - dosage and administration instructions;
        - any necessary warnings for the user, target species, administration or disposal of the product;
        - the withdrawal period, if relevant.
    - keep a record of the above information for at least five years.
- The ManSA holder must formulate the product in accordance with the prescribing veterinary surgeon's requirements.
- The ManSA holder must, in addition to the standard label as set out in the VMD ManSA guidance linked above, label the extemporaneous product in line with the full list of requirements in paragraph 13(2) of Schedule 3 to the Veterinary Medicines Regulations 2013 (see Annex), using the information provided by the prescribing veterinary surgeon as set out above.

For the avoidance of doubt, the VMR continue to apply. This is a statement of a temporary change to the standard VMD guidance on "Manufacturers of extemporaneous preparations for use under the cascade (ManSA)" only.

Annex: Labelling requirements

Veterinary Medicines Regulations 2013: paragraph 13(2) of Schedule 3

Supply of veterinary medicinal products for use under the cascade

13 (2) Unless the veterinary surgeon who prescribed the veterinary medicinal product both supplies the product and administers it to the animal in person, the person supplying it must label it (or ensure that it is labelled) with at least the following information—

(a) the name and address of the pharmacy, veterinary surgery or approved premises supplying the veterinary medicinal product;

(b) the name of the veterinary surgeon who has prescribed the product;

(c) the name and address of the animal owner;

(d) the identification (including the species) of the animal or group of animals;

(e) the date of supply;

(f) the expiry date of the product, if applicable;

(g) the name or description of the product, which should include at least the name and quantity of active ingredients;

(h) dosage and administration instructions;

(i) any special storage precautions;

(j) any necessary warnings for the user, target species, administration or disposal of the product;

(k) the withdrawal period, if relevant; and

(l) the words "Keep out of reach of children" and "For animal treatment only".