STATUTORY INSTRUMENTS

2024 No. 567

The Veterinary Medicines (Amendment etc.) Regulations 2024

PART 3

Amendments to Schedule 1 to the 2013 Regulations

Amendment to paragraph 51

64. For paragraph 51 (ampoules) substitute—

"**Package leaflet of veterinary medicinal products**

51.—(1) Subject to sub-paragraphs (5) and (7), a package leaflet must be supplied with each veterinary medicinal product.

(2) The package leaflet must provide the following information—

(a) the name and address of the marketing authorisation holder and of the manufacturer and, where applicable, the distributor;

(b) the name of the veterinary medicinal product, followed by its strength and pharmaceutical form;

(c) the qualitative and quantitative composition of any active substance;

(d) the target species, the dosage for each species, the method and route of administration and if necessary, advice on the correct administration;

(e) the indications for use;

(f) the contra-indications and adverse events;

(g) if applicable, the withdrawal period for each species, even if such a period is zero;

(h) special storage precautions, if any;

(i) information essential for safety or health protection, including any special precautions relating to use and any other warnings;

(j) the words "use take-back schemes for the disposal of any unused veterinary medicinal product or associated waste materials in accordance with local requirements and with any applicable national collection schemes";

(k) the marketing authorisation number;

(l) contact details for the marketing authorisation holder or its representative, as appropriate, for the reporting of suspected adverse events;

(m) classification of the veterinary medicinal product as referred to in the summary of product characteristics.

(3) Providing that it complies with the marketing authorisation, the package leaflet may include additional information concerning distribution, possession or any necessary precaution required, provided that this information is not promotional in character.

(4) The package leaflet must be in legible form and designed to be clear and understandable, in terms that are comprehensible to the general public.

(5) Only a package leaflet approved in the marketing authorisation may be published or included with the veterinary medicinal product.

(6) The Secretary of State may require the information set out in sub-paragraph (2) to be made available in written form or electronically, or both.

(7) Where the Secretary of State requires the leaflet to be made available electronically—

(a) an electronic package information leaflet which includes the information required by this paragraph must be provided in place of a leaflet in written form;

(b) the packaging of the veterinary medicinal product must include—

(i) a statement that the information which must be included on a package leaflet is provided electronically;

(ii) any necessary electronic link in order to access the relevant part of the website where the electronic package information leaflet is to be found;

(iii) a statement that a copy of the information in written form may be obtained on request; and

(iv) instructions on how to obtain such a copy.

(8) Any information required by this paragraph to be provided on a package leaflet in written form may be otherwise provided on the packaging of the veterinary medicinal product.”.