STATUTORY INSTRUMENTS

2024 No. 567

The Veterinary Medicines (Amendment etc.) Regulations 2024

PART 8

Amendments to Schedule 6 to the 2013 Regulations

New paragraphs 3A and 3B

157. After paragraph 3 insert—

"Register of persons placing veterinary medicinal products on the market (small pet animals)

- **3A.**—(1) A person placing the product on the market must be registered in accordance with this paragraph.
- (2) An application for registration in respect of that person must be submitted under sub-paragraph (4)—
 - (a) at least two months before that person places the product on the market, or
 - (b) where that person has already placed the product on the market, within six months of the date on which this provision comes into force.
- (3) Information may be submitted to the Secretary of State pursuant to sub-paragraph (2) prior to the date on which this provision comes into force, and in such a case—
 - (a) as regards an applicant for registration who has not already placed the product on the market, the period of two months is to be treated as having started on the date of submission;
 - (b) as regards an applicant for registration who has already placed the product on the market, the information is to be treated as having been submitted within the period of six months.
- (4) An application for registration must be made to the Secretary of State electronically and must include—
 - (a) the name and address of the person placing the product on the market;
 - (b) the individual making the application in respect of that person;
 - (c) the telephone number and email address of the individual mentioned in subparagraph (b);
 - (d) the name and address of the manufacturer of the product;
 - (e) the brand name of the product;
 - (f) the names and quantities of the active substances;
 - (g) the method and (where applicable) route of administration;
 - (h) the dosage instructions;

- (i) the category of animal mentioned in paragraph 1 for which the product is intended.
- (5) For the purposes of sub-paragraph (1) the Secretary of State must establish and maintain a register of persons placing on the market products to which this Schedule applies.
- (6) The particulars entered on the register must include the name and the address of the person mentioned in sub-paragraph (1).

Persons registered in accordance with paragraph 3A: annual return

- **3B.** At least once each calendar year a person registered under paragraph 3A must notify the Secretary of State in writing of the following in respect of each product placed on the market—
 - (a) the name and registered address of the person (if different from that listed on the register);
 - (b) the individual designated for the purpose of making the annual return under this paragraph;
 - (c) the telephone number and email address of the individual mentioned in subparagraph (b);
 - (d) the name and address of the manufacturer of the product;
 - (e) the brand name of the product;
 - (f) the names and quantities of the active substances;
 - (g) the method and (where applicable) route of administration;
 - (h) the dosage instructions;
 - (i) the category of animal mentioned in paragraph 1 for which the product is intended.".