
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 59

- 71.** In paragraph 59 (periodic safety update reports)—
- (a) in sub-paragraph (1)—
 - (i) for “records of all adverse reactions (including nil reports)” substitute “a summary of pharmacovigilance activity”;
 - (ii) for “a periodic safety update report” substitute “an annual benefit-risk report”;
 - (iii) omit the words from “, including” to the end;
 - (b) omit sub-paragraph (2);
 - (c) in sub-paragraph (3)—
 - (i) for “the United Kingdom” substitute “Great Britain”;
 - (ii) for “periodic safety update report” substitute “benefit-risk report”;
 - (iii) for the words from “request and—” to the end of the sub-paragraph substitute “request and, in any event, once in the course of every year during the period of validity of the authorisation”;
 - (d) in sub-paragraph (4) for “periods of notification” substitute “submission dates for the annual benefit-risk reports”;
 - (e) for sub-paragraph (5) substitute—

“(5) The report must include a statement regarding the benefit-risk balance of the veterinary medicinal product.”;
 - (f) for sub-paragraph (6) substitute—

“(6) The annual benefit-risk report must include—

 - (a) the volume of the product sold in the United Kingdom and in other countries in the period covered by the report, with the volume of the product sold in the United Kingdom in each calendar year identified;
 - (b) the notification of signals detected during the reporting period following pharmacovigilance activity in the United Kingdom or a country other than the United Kingdom for which further regulatory actions are required (including a summary of the regular review of adverse events carried out during the year); and
 - (c) where it appears from the observed data that there is cause for concern in relation to the safety of the product, recommendations on the need for further intervention by the Secretary of State.”;

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

- (g) omit sub-paragraphs (7) and (8);
- (h) in the heading for “Periodic safety update” substitute “Annual benefit-risk”.