Wytyczne dot. bezpieczeństwa farmakoterapii

Submitted by m.koszewski on Wed, 09/08/2023 - 08:21

- Wytyczne dobrej praktyki monitorowania bezpieczeństwa – **">guideline** [1] on veterinary good pharmacovigilance practices [2] (VGVP guideline [1]).

https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guideline-veterinary-good-pharmacovigilance-practices-vgvp-module-collection-recording-suspected_en.pdf [3]

https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guideline-veterinary-good-pharmacovigilance-practices-vgvp-module-signal-management_en.pdf [4]

https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guideline-veterinary-good-pharmacovigilance-practices-vgvp-module-veterinary-pharmacovigilance_en.pdf [5]

https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guideline-veterinary-good-pharmacovigilance-practices-vgvp-module-pharmacovigilance-systems-their_en.pdf [6]

https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guideline-veterinary-good-pharmacovigilance-practices-vgvp-module-controls-pharmacovigilance_en.pdf [7]

https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guideline-veterinary-good-pharmacovigilance-practices-vgvp-module-glossary_en.pdf [8]

- Terminy składania rocznych oświadczeń dot. bezpieczeństwa produktów leczniczych weterynaryjnych.

https://www.ema.europa.eu/documents/other/recommended-due-dates-submission-annual-statements-centrally-non-centrally-authorised-products-caps_en.xlsx [9]

- Formularz raportu dot. sygnału.

https://www.ema.europa.eu/documents/template-form/veterinary-signal-assessment-report-marketing-authorisation-holders_en.docx [10]

- Dokument Pytania & Odpowiedzi na temat prezentacji działań niepożądanych w drukach informacyjnych (CHPLW i ulotce informacyjnej).

https://www.ema.europa.eu/documents/other/questions-answers-describing-adverse-events-product-information-summary-product-characteristics-spc_en.pdf [11]

Links
[1] https://www.ema.europa.eu/en/glossary/guideline
[2] https://www.ema.europa.eu/en/glossary/good-pharmacovigilance-practices
[3] https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guideline-veterinary-good-pharmacovigilance-practices-vgvp-module-collection-recording-suspected_en.pdf

[4] https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guideline-veterinary-good-pharmacovigilance-practices-vgvp-module-signal-management_en.pdf
[5] https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guideline-veterinary-good-pharmacovigilance-practices-vgvp-module-veterinary-pharmacovigilance_en.pdf
[6] https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guideline-veterinary-good-pharmacovigilance-practices-vgvp-module-pharmacovigilance-systems-their_en.pdf
[7] https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guideline-veterinary-good-pharmacovigilance-practices-vgvp-module-controls-pharmacovigilance_en.pdf
[8] https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guideline-veterinary-good-pharmacovigilance-practices-vgvp-module-glossary_en.pdf
[9] https://www.ema.europa.eu/documents/other/recommended-due-dates-submission-annual-statements-centrally-non-centrally-authorised-products-caps_en.xlsx
[10] https://www.ema.europa.eu/documents/template-form/veterinary-signal-assessment-report-marketing-authorisation-holders_en.docx
[11] https://www.ema.europa.eu/documents/other/questions-answers-describing-adverse-events-product-information-summary-product-characteristics-spc_en.pdf