30 October 2026
EMA/247043/2026
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products

Draft agenda for the meeting on 3-5 November 2026

Chair: G. J. Schefferlie – Vice-chair: F. Hasslung Wikström

3 November 2026, 09:00 – 5 November 2026, 13:00 – virtual and Room 1D

Health & Safety Information

In accordance with the Agency's Health and Safety policy, delegates are to be briefed on health and safety and emergency information and procedures prior to the start of this meeting.

Disclaimer

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the CVMP meeting highlights once the procedures are finalised and start of referrals will also be available.

Of note, this agenda is a working document primarily designed for CVMP members and the work the Committee undertakes.

Declaration of interests

In accordance with the Agency's policy and procedure on the handling of competing interests, participants in this meeting are asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting will take place in full respect of the restricted involvement of CVMP members and, where relevant, experts attending the plenary meeting, as announced by the CVMP Secretariat at the start of meeting.

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/729522/2016).

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iii. Declaration of contacts between members and companies with regard to points on the agenda.

iv. Adoption of the minutes of the previous meetings: June, July, September and October 2026

v. Topics and experts' participation in discussions, rapporteur's meetings and breakout sessions held in advance or in the margins of the present CVMP meeting.

Scientific Advice Working Party (virtual)	Fri 30 Oct 26	10.00-13.00 (TBC)

1. Maximum residue limits

1.1. Opinions

No items

1.2. Oral explanations

No items

1.3. List of outstanding issues

1.3.1. Substance – EMA/V/MRL/006945 – bovine

Action: For adoption

Scientific overview and list of outstanding issues

1.4. List of questions

No items

1.5. Re-examination of CVMP opinions on maximum residue limits

No items

1.6. Other issues

1.6.1. Substance EMEA/V/MRL/007033/FULL/0001 – bees – SME

Action: For endorsement

Request from the applicant for an extension of the clock stop

2. Marketing authorisations

2.1. Opinions

2.1.1. Lotilaner / moxidectin / pyrantel / praziquantel – EMEA/V/C/006753/0000 – dogs

Indication: for the treatment of mixed external and internal parasitic infestations/infections by ectoparasites, cestodes and nematodes, when used against ectoparasites, cestodes and nematodes is indicated at the same time. Ectoparasites: For the treatment of tick (*Dermacentor reticulatus*, *Ixodes ricinus*, *I. hexagonus* and *Rhipicephalus sanguineus*) and flea (*Ctenocephalides felis* and *C. canis*) infestations in dogs. This veterinary medicinal product provides immediate and persistent killing activity for 1 month for ticks and fleas. The veterinary medicinal product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD). For the treatment of demodicosis (caused by *Demodex canis*). Cestodes: Treatment of infections with tapeworms (*Echinococcus multilocularis*, *E. granulosus*, *Taenia* spp., *Dipylidium caninum*). Gastrointestinal nematodes: For the treatment of infections with roundworms (*Toxocara canis* immature adults (L5) and adults, and *Toxascaris leonina* adults) and hookworms (*Ancylostoma caninum L4 larvae*, immature adults (L5) and adults, and *Uncinaria stenocephala* adults). Other nematodes: For the prevention of heartworm disease (*Dirofilaria immitis*). For the treatment of angiostrongylosis (*Angiostrongylus vasorum*). For the prevention of angiostrongylosis by targeting immature adult (L5) and adult stages of *Angiostrongylus vasorum*.

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.2. *Streptococcus suis* vaccine (recombinant protein) – EMEA/V/C/006777/0000 – pigs

Indication: for passive immunisation of progeny by active immunisation of pregnant sows and gilts to reduce clinical signs, mortality, bacterial load and pathological lesions in serosae, joints and organs which are associated with *Streptococcus suis* belonging to IdeSsuis genotype 1.1.

Action: For adoption

CVMP opinion CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.3. Canine distemper, canine adenovirus, canine parainfluenza virus vaccine (live), canine parvovirus vaccine (live, recombinant) and canine leptospirosis vaccine (inactivated) – EMEA/V/C/006876/0000 – dogs

Indication: for the active immunisation of dogs from 6 weeks of age onwards to prevent or reduce symptoms or lesions caused by CDV, CAV1, CAV2, CPV, CPi, *Leptospira interrogans* and *L. kirschneri*.

Action: For adoption

CVMP opinion, CVMP assessment report, product information

Action: For information

Summary of opinion

2.1.4. Verdinexor – EMEA/V/C/005902/0000 – dogs

Indication: for the treatment of lymphoma in dogs.

Action: For adoption

CVMP opinion CVMP assessment report, product information

Action: To note

Divergent positions

Action: For information

Summary of opinion

2.2. Oral explanations

2.2.1. Scovella – velagliflozin – EMA/V/C/006610 – horses

Indication: product intended for the treatment of hyperinsulinaemia and associated clinical signs (e.g., laminitis) in insulin-dysregulated horses and ponies not responsive to changes in husbandry and exercise regimen.

Action: Oral explanation to be held on 3 November 2026 at 14:15 CET

2.3. List of outstanding issues

2.3.1. Double-stranded RNA with nucleotide sequence complementary to the calmodulin mRNA of *Varroa destructor* – EMEA/V/C/006823/0000 – honey bees

Indication: for reduction of varroa mite (*Varroa destructor*) infestation to prevent varroosis in honey bees during the productive season or in the autumn going into overwintering.

Action: For decision

Need for oral explanation

Action: For adoption

Scientific overview and list of outstanding issues, comments on the product information

2.3.2. Mupirocin - EMEA/V/C/006638/0000 – dogs

Indication: for the treatment of canine localised pyoderma (i.e. superficial bacterial folliculitis, intertrigo, chin pyoderma and interdigital pyoderma) caused by methicillin resistant *Staphylococcus pseudintermedius* strains.

Action: For decision

Need for oral explanation

Action: For adoption

Scientific overview and list of outstanding issues, comments on the product information

2.4. List of questions

2.4.1. Imepitoin – EMEA/V/C/007013/0000 – dogs

Indication: for the reduction of the frequency of generalised seizures due to idiopathic epilepsy in dogs for use after careful evaluation of alternative treatment options. For the reduction of anxiety and fear associated with noise phobia in dogs.

Action: For adoption

Scientific overview and list of questions, comments on the product information

2.4.2. Piscirickettsiosis vaccine (live) for atlantic salmon – EMEA/V/C/007035/0000 – atlantic salmons

Indication: for active immunisation of atlantic salmon (Salmo salar) against piscirickettsiosis to reduce mortality, lesions and clinical signs of disease caused by *Piscirickettsia salmonis*.

Action: For adoption

Scientific overview and list of questions, comments on the product information

2.4.3. Canine adipose tissue-derived mesenchymal stromal cells – EMEA/V/C/007017/0000 – dogs

Indication: treatment of clinical symptoms associated with osteoarthritis in dogs.

Action: For adoption

Scientific overview and list of questions, comments on the product information

2.4.4. Aeromonas veronii, strain AL 21803, inactivated – EMEA/V/C/006991/0000 – seabass

Indication: for active immunisation of seabass to reduce mortality caused by *Aeromonas veronii*.

Action: For adoption

Scientific overview and list of questions, comments on the product information

2.5. Re-examinations of CVMP opinions

2.5.1. Scovella – velagliflozin – EMA/V/C/006610 – horses

Indication: product intended for the treatment of hyperinsulinaemia and associated clinical signs (e.g., laminitis) in insulin-dysregulated horses and ponies not responsive to changes in husbandry and exercise regimen.

Action: For adoption

Final CVMP opinion, final CVMP assessment report

2.6. Other issues

2.6.1. Buprenorphine hydrochloride – EMA/V/C/006917 – mice, rats, rabbits

Action: For decision

Request for extension of the clock stop

2.6.2. Aurylum – florfenicol / mometasone furoate / terbinafine – EMEA/V/C/006831/0000 – dogs

Action: For decision

Request for extension of the clock stop

3. Variations to marketing authorisations

3.1. Opinions

3.1.1. Syvazul BTV 3 – bluetongue virus vaccine (inactivated) – EMA/VRA/0000359275 – sheep, cattle

Variation requiring assessment: to fulfil two SOBs: completion of the development of the ELISA potency test for the BTV 3 antigen and to provide the study of duration of immunity in sheep.

Rapporteur: R. Breathnach, Co-Rapporteur: J. Poot

Action: For adoption

CVMP opinion, CVMP assessment report, product information

3.1.2. Hepizovac – epizootic haemorrhagic disease vaccine (inactivated) – EMA/VRA/0000356582 – cattle

Variation requiring assessment: to fulfil the specific obligation regarding the stability studies (up to 21 months) to confirm the accepted shelf life of 18 months under the recommended storage conditions for the finished product.

Rapporteur: J. Poot, Co-Rapporteur: L. Nepejchalová

Action: For adoption

CVMP opinion, CVMP assessment report, product information

3.1.3. Orbyk EHD – epizootic haemorrhagic disease vaccine (recombinant protein) – EMA/VRA/0000358791 – cattle

Variation requiring assessment: to fulfil the following obligations of the marketing authorisation under exceptional circumstances: to provide the complete validation report for the potency test in the finished product; to support the in-use shelf life of 10 hours by potency data.

Rapporteur: E. Werner, Co-Rapporteur: J. Poot

Action: For adoption

CVMP opinion, CVMP assessment report, product information

3.1.4. Zenrelia – ilunocitinib – EMA/VRA/0000377937 – dogs

Variation requiring assessment: to implement the outcome of the MAH's signal management process. In addition, the applicant took the opportunity to introduce some editorial changes.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

3.1.5. Credelio – lotilaner – EMA/VRA/0000358561 – cats

Variation requiring assessment: change(s) to therapeutic indication(s) in cats - addition of a new therapeutic indication or modification of an approved one: treatment of ear mite infestations (*Otodectes cynotis*).

Rapporteur: R. Breathnach, Co-Rapporteur: G. Kulcsár

Action: For adoption

CVMP opinion, CVMP assessment report, product information

3.2. Oral explanations

No items

3.3. List of outstanding issues

3.3.1. Lotilaner / Milbemycin Elanco – lotilaner / milbemycin oxime – EMA/VRA/0000344590 – dogs

Variation requiring assessment: to change the legal status from "subject to prescription" to "not subject to prescription". In addition, the MAH takes the opportunity to propose a change in the adverse events section relating to "muscle tremor".

Rapporteur: R. Breathnach, Co-Rapporteur: G. Kulcsár

Action: For decision

Need for oral explanation

Action: For adoption

List of outstanding issues, comments on the product information

3.3.2. Tessie – tasipimidine – EMA/VRA/0000345377 – dogs

Variation requiring assessment: to modify the indication for use and to amend the product information as regards the age and bodyweight of target population, duration of treatment and administration instructions (including updated pictograms).

Rapporteur: K. Boerkamp, Co-Rapporteur: S. Louet

Action: For decision

Need for oral explanation

Action: For adoption

List of outstanding issues, comments on the product information

3.4. List of questions

3.4.1. NexGard Combo – eprinomectin / esafoxolaner / praziquantel – EMA/VRA/0000369947 – cats

Variation requiring assessment: change(s) to therapeutic indication(s) - addition of a new therapeutic indication or modification of an approved one: treatment of lice infestation (caused by *Felicola subrostratus*). Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet - for changes due to new quality, preclinical, clinical or pharmacovigilance data: to add the therapeutic benefit regarding lungworms infection (*Aelurostrongylus abstrusus* and *Troglostrongylus brevior*). In addition, the applicant took the opportunity to align the product information with QRD version 9.1, make editorial changes and correct an error related to the invented name of the product.

Rapporteur: A. Golombiewski, Co-Rapporteur: N.C. Kyvsgaard

Action: For adoption

List of questions, comments on the product information

3.5. Re-examinations of CVMP opinions on variations requiring assessment

No items

3.6. Other issues

No items

4. Referrals and related procedures

4.1. Union interest referral under Article 82 of Regulation (EU) 2019/6

No items

4.2. Union interest referral under Article 82 based on Article 129(3) of Regulation (EU) 2019/6

No items

4.3. Procedure under Article 70(11) of Regulation (EU) 2019/6 due to lack of consensus between Member States in the SPC harmonisation procedure

No items

4.4. Request for clarification from the European Commission under Article 54(8) of Regulation (EU) 2019/6 on a CMDv review procedure

No items

4.5. Request from the European Commission under Article 130(4) of Regulation (EU) 2019/6 on suspending, revoking or varying the terms of centrally authorised products

No items

4.6. Request for a scientific opinion/advice under Articles 141(1)(c), 141(1)(e) or 141(1)(i) of Regulation (EU) 2019/6

No items

4.7. Other issues

Information on certain topics discussed under section 4.7 cannot be released at the present time as it is deemed to be confidential

No items

4.7.1. Referrals

No items

5. Post-authorisation issues for marketing authorisations

Information relating to GMP, pharmacovigilance inspections, supervision and sanctions will not be published as it would undermine the purpose of such inspections.

5.1. Pharmacovigilance

5.1.1. Strangvac – Streptococcus equi vaccine (recombinant proteins) – EMA/VS/0000376997, EMA/VS/0000371670

Signals on and musculoskeletal disorder NOS/reluctant to move/muscle stiffness/lameness and anorexia/difficulty eating NOS.

Rapporteur: M. Blixenkrone-Møller, Co-Rapporteur: E. Werner

Action: For adoption

CVMP assessment report

5.2. Post-authorisation measures

No items

5.3. Inspections and controls

No items

5.4. Re-examination of limited markets and exceptional circumstances authorisations

5.4.1. Vaxxinact H5 – avian influenza vaccine (subunit recombinant) – EMA/S/0000369550

Scope: to apply for the annual re-examination of the marketing authorisation Vaxxinact H5 in line with Article 27(3) of Regulation (EU) 2019/6.

Rapporteur: M. O'Grady, Co-Rapporteur: J. Poot

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

5.4.2. Vaxxitek HVT+IBD+H5 – avian influenza vaccine (live recombinant) – EMA/S/0000365375

Scope: to apply for the annual re-examination of the marketing authorisation for Vaxxitek HVT+IBD+H5 in line with Article 27(3) of Regulation (EU) 2019/6.

Rapporteur: E. Dewaele, Co-Rapporteur: J. Poot

Action: For adoption

CVMP opinion

5.5. Others

No items

6. Working parties

Information relating to certain topics discussed under section 6 cannot be released at the present time as it is deemed to be commercially confidential.

6.1. Antimicrobials Working Party (AWP)

6.1.1 Draft work plan for AWP 2027

Action: For discussion

6.2. Environmental Risk Assessment Working Party (ERAWP)

6.2.1. Verbal report on ERAWP meeting held on 13-14 October 2026

Action: For information

6.2.2. Draft work plan for ERAWP 2027

Action: For discussion

6.3. Efficacy Working Party (EWP-V)

6.3.1. Verbal report on EWP-V meeting held on 13-14 October 2026

Action: For information

6.3.2. Guideline on veterinary medicinal products controlling *Varroa destructor* parasitosis in bees

Action: For discussion

6.3.3. Guideline on dossier requirements for anticancer veterinary medicinal products

Action: For discussion

6.3.4. Draft work plan for EWP-V for 2027

Action: For discussion

6.4. Immunologicals Working Party (IWP)

6.4.1. Reflection paper on the use of heat treatment to inactivate endogenous retroviruses in live immunological veterinary medicinal products

Action: For adoption

6.5. 3Rs Working Party (3RsWP)

6.5.1. Election for Vice-chair of 3RsWP

Action: For election

6.5.2. Draft consolidated 3-year non-clinical domain work plan 2027-2029

Action: For discussion

6.5.3. Guideline on principles of regulatory acceptance of 3Rs testing approaches

Action: For discussion

6.6. Novel Therapies & Technologies Working Party (NTWP)

6.6.1 Appointment of a new NTWP member – recommendation from the veterinary domain

Action: For endorsement

6.6.2. Draft work plan for NTWP for 2027

Action: For discussion

6.7. Pharmacovigilance Working Party (PhVWP-V)

6.7.1. Verbal report on PhVWP-V meeting held on 28 October 2026

Action: For information

6.7.2. Revised VGVP Module: signal management – Medically Important (MI) VeDDRA terms list

Action: For adoption

6.8. Quality Working Party (QWP)

6.8.1. Verbal report on QWP meetings held in September and October 2026 and IPs meeting October 2026

Action: For information

6.8.2. Draft 3-year QWP work plan 2027-2029

Action: For discussion

6.9. Scientific Advice Working Party (SAWP-V)

6.9.1. Verbal report on SAWP-V meeting held on 30 October 2026

Action: For information

6.9.2 Appointment of a new SAWP-V member – recommendation from the Veterinary Domain

Action: For endorsement

6.10. Safety Working Party (SWP-V)

6.10.1. Appropriateness of subchronic and chronic toxicity studies in dogs for ADI derivation

Action: For adoption

6.10.2. Draft work plan for SWP-V for 2027

Action: For discussion

6.11. Other working party and scientific group issues

6.11.1. Expert groups mandate

Action: For adoption

6.11.2. Revised Working Parties mandate

Action: For adoption

6.11.3. Draft work plan ADRA temporary Working Party for 2027

Action: For discussion

7. Other scientific matters

Information on scientific matters or other critical issues cannot be released at the present time as it is deemed to be confidential

7.1. MRL issues

No items

7.2. Environmental risk assessment

No items

7.3. Antimicrobial resistance

7.3.1. Fifth (5th) JIACRA report

Action: For adoption

7.4. Pharmacovigilance

No items

7.5. Vaccine antigen master file (VAMF) certification

Information on this section cannot be released at the present time as it is deemed to be commercially confidential.

No items

7.6. Platform technology master file (PTMF) certification

Information on this section cannot be released at the present time as it is deemed to be commercially confidential.

No items

7.7. Other issues

7.7.1. Nitrosamine impurities in VMPs

Action: For adoption

CVMP established practice on nitrosamines in VMPs

8. Co-operation with other EU or International bodies

Information on certain topics discussed under section 8 cannot be released at the present time as it is deemed to be commercially confidential.

8.1. VICH

8.1.1. Revision of VICH GL47 on Comparative Metabolism Studies in Laboratory Animals

Action: For endorsement

EU comments on the revised GL47.

8.1.2. Review of VICH GLs that have not been reviewed in the last 5 years

Action: For endorsement

EU proposal on the need for review VICH GLs in 2026

8.1.3. Agendas and supporting documents for the VICH Steering Committee and forum meetings to be held in Tsukuba, Japan, 16-19 November 2026

Action: For discussion

Agenda for the 45th VICH Steering Committee meeting and 19th VICH forum meeting

8.2. Codex Alimentarius

No items

8.3. Other EU bodies and international organisations

8.3.1 Development of guidance on the use of biomarkers of effect in risk assessment (joint mandate EFSA-EMA-ECHA)

Action: For discussion

Concept paper on guidance on the use of biomarkers of effect in risk assessment, jointly by EFSA, EMA and ECHA

9. Procedural and regulatory matters

Information relating to limited markets classifications, new applications and eligibility requests for Union marketing authorisations and certain regulatory matters cannot be released at the present time as it is deemed to be commercially confidential.

9.1. Limited markets classifications according to Article 4(29) and confirmation of eligibility for authorisation according to Article 23 of Regulation (EU) 2019/6

No items

9.2. Eligibility for centralised procedures, appointment of rapporteurs, co-rapporteurs and peer reviewers

9.2.1. Summary of eligibility and table of offers from rapporteurs

Action: For decision

9.2.2. Eligibility request

Action: For decision

9.2.3. Eligibility request

Action: For decision

9.2.5. Eligibility request

Action: For decision

9.2.6. Eligibility request for centralised procedure and the multi-strain dossier approach

Action: For decision

9.2.7. Eligibility request

Action: For decision

9.3. Regulatory matters

9.3.1. Draft EMA Q&A on VRAs for non-POM (non-Prescription Only Medicines) VMPs

Action: For information

10. Organisational and strategic matters

10.1. Verbal report on veterinary domain meeting held on 12 October 2026

Action: For information

10.2. Network Data Steering Group (NDSG) – CVMP representative

Action: For endorsement

10.3. Revision of the Mandate, objectives and rules of procedure for the veterinary domain

Action: For discussion

10.4. Draft CVMP work plan for 2026

Action: For discussion

11. CMDv

11.1. Verbal report on CMDv meetings held in September 2026 and October 2026

Action: For information

12. Legislation

No items

13. Any other business

13.2. Meeting highlights

Action: For comments

Meeting highlights

14. Annex

3. Variations to marketing authorisations

3.1. Opinions

Credelio Plus – lotilaner / milbemycin oxime – EMA/VRA/0000322260 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Clynav – salmon pancreas disease vaccine (recombinant DNA plasmid) – EMA/VRA/0000358332 – atlantic salmons

Variation requiring assessment: quality-related changes.

Rapporteur: P. McNeill

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Porcilis PCV M Hyo – porcine circovirus and porcine enzootic pneumonia vaccine (inactivated) – EMA/VRA/0000358527 – pigs

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Bluevac 3 – bluetongue virus vaccine (inactivated) – EMA/VRA/0000360349 – sheep and cattle

Variation requiring assessment: quality-related changes.

Rapporteur: E. Werner

Action: For adoption

CVMP opinion, product information

Action: For endorsement

Rapporteur's assessment report

Arti-Cell Forte / RenuTend – alisvetcel / tesrivetcel – WS EMA/VRA/0000341950 – horses

Variation requiring assessment: quality-related changes.

Rapporteur: F. Hasslung Wikström

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Numelvi – atinvicitinib – EMA/VRA/0000377912 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: R. Breathnach

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Meloxidyl – meloxicam – WS EMA/VRA/0000347915 – cats, dogs

Variation requiring assessment: quality-related changes.

Rapporteur: H. Bremer

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report, product information

Felpreva – tigolaner / emodepside / praziquantel – EMA/VRA/0000357692 – cats

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

Bonqat – pregabalin – EMA/VRA/0000365716 – cats

Variation requiring assessment: quality-related changes.

Rapporteur: M. O'Grady

Action: For adoption

CVMP opinion

Action: For endorsement

Rapporteur's assessment report

3.4 List of questions

Steflonta – tigilanol tiglate – EMA/VRA/0000378395 – dogs

Variation requiring assessment: quality-related changes.

Rapporteur: K. Boerkamp

Action: For adoption

List of questions

NexGard Combo and Broadline – esafoxolaner / eprinomectin / praziquantel and fipronil / (S)-methoprene / eprinomectin / praziquantel – EMA/VRA/0000335335 – cats

Variation requiring assessment: quality-related changes.

Rapporteur: A. Golombiewski

Action: For adoption

List of outstanding issues

4. Referrals and related procedures

4.7. Other issues

5. Post-authorisation issues for marketing authorisations

5.1 Pharmacovigilance

Signal evaluation and recommendations

Action: For adoption

Outcome of the signal management process, list of finalised signals

5.2 Post-authorisation measures

Stelfonta – tigilanol tiglate – EMA/PAM/0000373055 – dogs

Rapporteur: K. Boerkamp

Action: For endorsement

Rapporteur's assessment report

6. Working parties

6.5. 3Rs Working Party (3RsWP)

NC and NAMs ESEC nominations

Action: For information

NC and NAMs ESEC nominations

6.8 Quality Working Party (QWP)

Quality Chemical ESEC nominations

Action: For adoption

7. Other scientific matters

7.7. Other issues

8. Co-operation with other EU or International bodies

8.1. VICH

9. Procedural and regulatory matters

9.1. Limited markets classifications according to Article 4(29) and confirmation of eligibility for authorisation according to Article 23 of Regulation (EU) 2019/6

9.3. Regulatory matters

Invented names