Monograph Development Framework

Purpose: To define a transparent, reproducible process for developing species-specific pharmacology monographs that integrate V-GRADE evidence appraisal, Delphi consensus development, and AAP-16 clinical formatting.

This framework provides a full audit trail from primary evidence acquisition to consensus-validated publication for MSTT 2 and VetConsensus repositories.

1. Registration and Governance

- Each monograph is registered within the VetConsensus master index by active substance and species stream (Chelonian, Avian, Rabbit, Hedgehog, etc.).
- The Monograph Administrator (MA) appoints the author, editor, and reviewer team.
- Contributors complete conflict-of-interest declarations and contributor agreements.
- A dedicated Zotero folder and shared workspace are created for citation management and traceability.

2. Literature Acquisition and Evidence Mapping

Databases: PubMed | ScienceDirect | CAB VetMed | RCVS Knowledge | British Library | EMA | FDA | WOAH | AVMA archives.

- Only peer-reviewed or regulator-verified literature is admissible.
- Search terms are standardised (active substance, species, PK/PD, toxicity, clinical use).
- Each reference is tagged to one or more **V-GRADE evidence domains (D1–D5):**

Domains	Descriptor	Primary Focus
D1	Dose Accuracy	Study design quality, pharmacokinetic reliability, dosing precision.
D2	Clinical Suitability	Species relevance, formulation practicality, clinical alignment.
D3	Therapeutic Recommendations	Quality and applicability of treatment regimens, integration with practice.
D4	Safety Profile	Adverse effects, contraindications, toxicity data, tolerability.
D5	Efficacy	Magnitude and reproducibility of response, comparative outcomes.

Evidence is mapped in a **Species × Domain matrix** to visualise data distribution and highlight gaps.

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3. Evidence Review and V-GRADE Appraisal

Each reference is critically appraised using **V-GRADE**, adapted from the international GRADE system.

- Certainty of evidence is rated (High | Moderate | Low | Very Low).
- Study validity, precision, and bias are recorded.
- Weighted scores generate Domain-Weighted Evidence Profiles (DWEPs).
- Narrative evidence summaries per domain are written for inclusion in the monograph.

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4. Drafting the Primary Monograph

Author Team Output:

- Synthesises data across D1–D5 domains.
- Drafts the preliminary dosing rationale, pharmacokinetic and pharmacodynamic overview.
- Incorporates the detailed **Therapeutics Section** (route, dose, interval, duration, preparation, administration, monitoring, special considerations).
- References are Harvard-formatted with Zotero citation keys.
- Internal editorial review ensures consistency with VetConsensus style and AAP-16 formatting.

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5. Delphi Review (Consensus Development and Validation)

The Delphi process is both **collaborative** and **evaluative**, allowing experts to develop and refine the monograph before final consensus.

Panel Composition

- ≥ 10 blinded panellists representing clinical, academic, and pharmacological expertise.
- Panellists receive the full monograph, evidence tables, and scoring guidance.

Round 1 – Exploratory Development

- Panellists provide **substantive feedback** on content and structure across D1–D5.
  Free-text comment fields permit additions, clarifications, and data suggestions.
- The editorial team integrates validated revisions into a **Round 1 Revision Draft**.

Round 2 – Structured Refinement

- Panellists review the revised draft with anonymised summaries of Round 1 feedback.
- Further refinements are invited; quantitative scoring begins but qualitative input remains open.
- The outcome is a technically mature **Pre-Consensus Draft**.

Round 3 – Consensus Validation

- Focus shifts to **agreement** rather than development.
- Panellists rate each domain (D1–D5) on a 1–9 Likert scale.
- Consensus is achieved at ≥ 80 % agreement (median ± IQR thresholds).

Outputs

- **Quantitative:** domain-specific consensus scores and confidence intervals.
- **Qualitative:** documented expert contributions demonstrating how content evolved.
- All Delphi datasets and revisions are archived for transparency and audit.

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6. Consensus Monograph Finalisation

- The final monograph integrates Delphi-weighted scores, refined text, and domain summaries.
- Appendices include V-GRADE evidence tables and Delphi statistics.
- Authorship, editorial, and panellist credits are published.
- The document is archived with DOI and version control (e.g. VetConsensus 2026 v1).

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7. Publication and Integration

- Consensus monographs are supplied to:
    - *MSTT 2* editorial team (for integration into therapeutic chapters).
    - VetConsensus restricted professional repository.
    - Partner organisations (Many options) under member-access arrangements.
- Reviews occur every three years or upon emergence of significant new data.

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8. Quality Assurance and Audit

- Complete audit trail retained (search logs, V-GRADE appraisals, Delphi comments, scores).
- QA ensures compliance with D17 structure, V-GRADE weighting, and AAP-16 Therapeutics standards.
- Metadata archived for retrieval and citation export.

Outcome

This **D17-integrated framework** unites rigorous evidence appraisal (V-GRADE), collaborative expert development (Delphi), and structured therapeutic application (AAP-16).

Our developing and dynamic framework ensures every VetConsensus monograph is scientifically robust, transparently developed, and directly applicable in clinical and educational contexts.

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