Australian Government

Australian Pesticides and Veterinary Medicines Authority

Update on GMP Code Review

CAPSIG / ISPE / PDA Seminar

6th May 2026

Malcom Hammond

Director

Manufacturing Quality and Licensing (MQL) & Assurance Section

Science and Assurance Branch

The APVMA acknowledges the Traditional Custodians of Australia and their continuing connection to land and sea, waters, environment and community. We pay our respects to the Traditional Custodians of the lands we live and work on, their culture, and their Elders past and present.

To be discussed

- Progress of the revision
- GMP Code Review Working Group
- What are the major changes?
- What is the timeline, and will there be an implementation period?

Current Auditing

All audits are conducted against the current legislation and GMP Code:

- *Agricultural and Veterinary Chemicals Code (Manufacturing Principles) Determination 2014*
- Australian code of Good Manufacturing Practice for veterinary chemical products (Code of GMP / GMP Code)

How far have the APVMA progressed in the revision?

- Consultants revised the current Code of GMP in 2024
- APVMA reviewed this revised Code of GMP in late 2024 / early 2025
- Draft revised Code of GMP provided to Industry Liaison Consultative Forum (ILCF) and Authorised Auditors for comments / feedback
- Comments / feedback provided by August 2025
- Strong stakeholder feedback at the Animal Health Industry Day (26 August 2025)

Proposed major changes at Animal Health Industry Day

Core elements

- Product quality review
- Quality Risk Management
- Computers & validation
- Cross-contamination control
- On-going stability programme

Annexes

- 1&2 Sterile & Biological products (not to PIC/s)
- 6 Premixes, supplements & biological feed additives
- 7 Sampling of starting and packaging materials
- 8 Reference and retention samples
- 9 Computerised systems
- 10 Qualification and validation
- 11 Ionising radiation
- 12 Template for site master file
- 13 Quality Risk Management (voluntary)

GMP Code Review Working Group

Composition of the Working Group

Chaired by Director | MQL & Assurance and one member from:

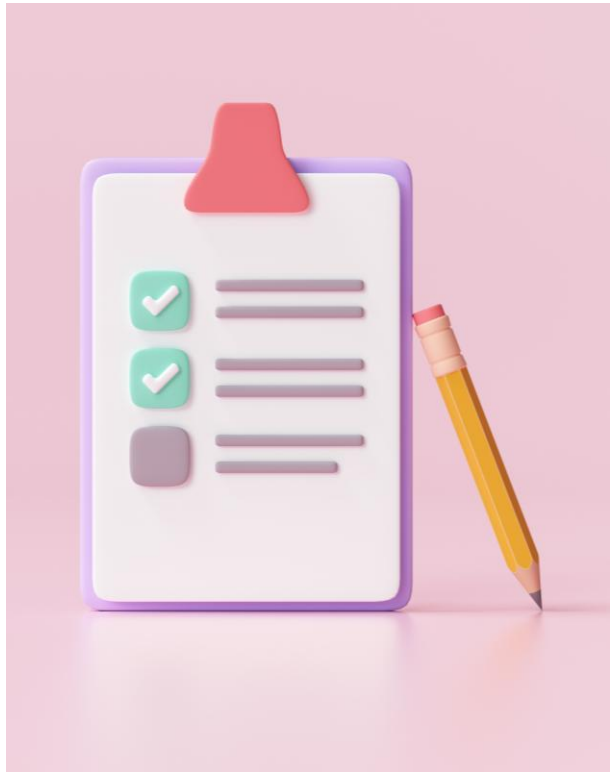
- Australian Pesticides and Veterinary Medicines Authority (in addition to Chair)
- APVMA-authorised auditors
- Animal Medicines Australia Limited (AMA)
- Veterinary Manufacturers and Distributors Association (VMDA)
- Food Ingredients and Additives Association of Australia (FIAAA)

Purpose of Working Group

The Working Group (WG) is intended to:

- To work with MLS on revising the GMP Code to get reasonable agreement on the revised GMP Code before public consultation.
- Provide information or comment on areas where there would be regulatory burden to the revised GMP Code.

The WG will not consider or be involved in regulatory decisions.



Productive discussions

- Robust discussions on the revised GMP Code
- Meaning / terminology of words i.e. “must”, “should”, “required”, “will”, etc. Definitions of words / phrases
- What annexes are needed
- Consideration of both industry and auditor perspectives
- Guidance documents for both industry and auditors

- WG nearing end of reviewing revised GMP Code

What are the key changes?

1. Annual Management Review
2. Supplier evaluation
3. On-going Stability Programme
4. Qualification / Validation life-cycle

Annual Management Review

Acknowledgement by the WG:

- Annual management review should be bare minimum (ISO 22000 - used in the food and beverage industries including stockfeed i.e. Feed Additive and preMixture Quality System (FAMI-QS)
- Integrates with ISO 9001 (Quality Management)
- Hazard Analysis and Critical Control Points (HACCP) principles
- Review in relations to manufacturing risks and mitigation

- Alternatively, manufacturers can do Product Quality Reviews (PQRs). This will be a business decision

Supplier evaluation

- Has an evaluation of supplier been conducted i.e. via audit or desktop assessment? What are the risks?
- Frequency of evaluation?
- Sampling and testing of starting and packaging materials
- Rationale and justification of frequency of testing

Example:

- Active substances i.e. BP, EP, USP
  - Different synthetic pathways, solvents used and related substance profiles
  - Impurities classification i.e. genotoxicity

On-going Stability Programme

Instances where stability should be conducted:

- Major deviation in the manufacturing process
- Change in Active Substance supplier
- Change in excipient supplier
- Change in primary packaging supplier (product contact)

Qualification / Validation life-cycle

From WG discussions:

- Qualification / validation life-cycle of equipment and manufacturing processes is not well understood
- Cleaning validation
- Auditable aspects should be in core chapters
- Concurrent validation and what requirements are expected
- Guidance instead of having an annex

What is the timeline, and will there be an implementation period?

- June 2026 – Start of public consultation
- September 2026 – Finish of public consultation
- Q4 2026 – Publication of new GMP Code
- 2027-2028 – Implementation phase
  - All audits conducted during this time will be to the current GMP Code
  - Observations / recommendations will be made in relation to the new GMP Code
  - Drafting of guidance documentation
    - These will be drafted, reviewed with the ILCF before public consultation, and then published
- 2029 - All audits conducted to the new GMP Code

Key Points

- Revising the Code of GMP:
  - WG close to finalizing Code of GMP
  - Public consultation June 2026
  - 2 Year implementation period
  - During transition, audits will be to the current Code of GMP with recommendations to the new code

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EU update for export

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To be discussed

- EU implementation Acts
- Does this change GMP evidence process?
- Future changes?

EU Regulations

- **EU published new implementing Regulations for veterinary medicines in October 2025**:
  - Commission Implementing Regulation (EU) 2025/2091 (for GMP of finished products)
  - Commission Implementing Regulation (EU) 2025/2154 (for GMP of active substances used as starting materials).

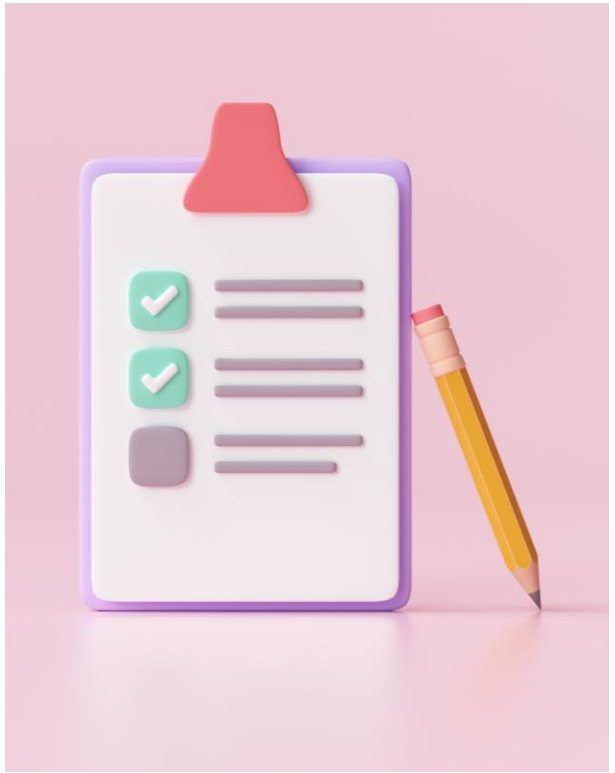
- Effective on 16 July 2026

GMP Audits / Inspections

- There is **no change** to current processes with the TGA conducting inspections for exporting products to the EU for veterinary medicines
  - Letter from the European Commission (2025) advising no change to the EU-Australian Mutual Recognition Agreement (MRA)
  - Confirmed by EMA earlier this year (March 2026)

Future changes

- APVMA is having discussion with the Department of Agriculture, Fisheries and Forestry (DAFF) about what will be required for APVMA to conduct audits of veterinary medicines for export to EU
- Discussions with the European Medicines Agency Inspector Working Group with how the APVMA can be recognised as an “Official Inspection Services”
- Early stages of the process



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Questions?