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Dear Mr Deller

Re: Submission to Draft Revised Australian code of Good Manufacturing Practice for veterinary chemical products (the GMP Code)

Thank you for the opportunity to provide feedback on the *Draft Revised Australian code of Good Manufacturing Practice for veterinary chemical products* (the GMP Code) following APVMA's review and amendments. Animal Medicines Australia (AMA) is pleased to provide the following comments and trust that they will assist in the next steps of this review process.

Yours Sincerely,

Dr Charmian Bennett
Director, Science and Regulatory Policy
Animal Medicines Australia

Unsigned for electronic submission

SUBMISSION TO THE

Draft Revised Australian code of Good Manufacturing Practice for veterinary chemical products (the GMP Code)

20 November 2026

Animal Medicines Australia

Introduction

Animal Medicines Australia (AMA) is the peak body representing the leading animal health companies in Australia. AMA member companies are the innovators, manufacturers, formulators and registrants of a broad range of veterinary medicine products that prevent, control and cure disease across the companion animal, livestock and equine sectors.

AMA supports a contemporary and effective GMP framework that maintains confidence in product quality, safety and efficacy while supporting continued access to veterinary medicines. However, AMA considers that the draft GMP Code requires substantial revision before it is finalised. Our concerns and recommendations are set out below.

1. Executive summary

- AMA does not support finalising the draft in its current form.
- AMA considers that further consultation is needed on a revised text alongside its accompanying guidance.
- Staged implementation and transition arrangements for established systems would be welcomed.

AMA supports updating the GMP Code to reflect contemporary manufacturing standards and changes in practice since the 2007 Code was implemented. The draft contains useful contemporary elements, including greater attention to quality systems, risk management, validation, data integrity and lifecycle oversight. However, in several areas it goes beyond an update of the Australian framework and risks operating as a de facto PIC/S-level manufacturing regime in the absence of a demonstrated risk-based justification for each additional requirement.

The Australian industry has been clear and consistent in its support of the GMP Code update, but equally clear and consistent in not supporting to a blanket adoption of the PIC/S GMP Code. Companies who choose to export to countries that do not recognise the APVMA GMP Code, do so based on a commercial financial decision that includes the additional costs to access those markets, and a mechanism for those manufacturers to access PIC/S-accredited audits is well established. The flip side is that in situations where a company does not wish to export to countries that do not recognise the APVMA GMP Code, the additional costs of manufacture to PIC/S-level should not be imposed on them, to be passed on to end users and the detriment of Australian consumers.

AMA's priority is to protect product quality through requirements that are proportionate, practical and capable of supporting continued supply across product lines, companies and market segments. The Code must distinguish mandatory baseline requirements from non-binding guidance and recognise scientifically justified equivalent approaches. GMP requirements must reflect product risk, manufacturing scale, production frequency, established process knowledge and the manufacturing model and approaches to compliance must be assessed through a documented risk-assessment process, rather than against an assumed rigid default.

Priority areas for amendment in the draft Code include product quality reviews, ongoing stability programmes, quality risk management, validation and concurrent validation, sterile manufacturing, contract manufacture, system-generated audit trails, cross-contamination controls and records

requirements. The APVMA must also consider cumulative compliance costs, specialist and facility capacity, additional animal use and the implications for product availability.

2. Introduction and operating environment

The veterinary medicines industry supports animal health and welfare across the livestock, equine and companion animal sectors. Continued product availability depends on a regulatory framework that maintains confidence in quality, safety and efficacy while recognising the commercial realities of a small and diverse Australian market. APVMA's GMP policy is critical to supporting innovation, productivity, local manufacturing capability and the responsible use of resources.

The commercial reality of veterinary pharmaceutical manufacturing in Australia is inadequately considered in the draft GMP Code. Increasing administrative, financial and regulatory burdens, recurring compliance costs, limited specialist capacity, reliance on contract manufacturers and overseas supply chains are critical material considerations for Australian registrants. The increasing burdens disproportionately affect Australian manufacturing and innovation, particularly small market/niche products which address critical animal health needs, and thereby reducing consumer choice.

Smaller companies and low-volume/small market, or 'niche', products are particularly exposed to changes in the cost base for their products, where additional testing, review cycles, stability chamber capacity, staff time, audit duration and service fees will affect the viability of maintaining individual products. The loss of substantial numbers of products and/or pack sizes is a genuine and foreseeable risk.

A likely consequence of the draft Code will be the loss of local manufacturing capacity and capability, with priority given to overseas manufacturing sites. This directly contradicts the findings of the Australian Productivity Commission that excessive bureaucracy, red tape and regulatory burdens significantly stall economic growth and productivity, and the current government agenda specifically aims to support the Australian manufacturing industry. Generally speaking, animal health products are less profitable than human health products. Complying with the requirements of the draft Code will bring additional costs that pose genuine risks to the availability of veterinary medicines in Australia.

Pharmaceutical manufacture is a highly specialised industry and once lost, it is rarely replaced. The loss of local manufacturing capability and expertise will risk the reliable supply of critical veterinary medicines, and put Australia at risk of supply disruptions due to increasingly complex and volatile global trade dynamics and supply chain vulnerabilities.

3. Overall position and principles for revision

AMA acknowledges that the current 2007 Code is dated and requires some update, and this review activity was mutually accepted by APVMA and industry as an important opportunity to *modernise* Australian GMP requirements. To support and protect Australia's local manufacturing and pharmaceutical industry, the update needed to aim for a moderate position where dated requirements are brought up to contemporary standards and reflect contemporary practice. However AMA considers that the draft GMP Code does not reflect this objective and for the majority of revisions, seeks to impose the highest available international standard.

An Australian GMP Code must establish the baseline requirements necessary to hold a manufacturing licence and provide flexibility for different systems where equivalent control and product-quality outcomes can be demonstrated.

AMA considers that the update of the Australian GMP Code should reflect the following framework:

1. The **Manufacturing Principles** establish the legal and regulatory baseline;
2. The **GMP Code** sets out the minimum expected outcomes and core controls; and
3. The **Supporting Guidance** describes acceptable approaches to meeting GMP Code requirements and auditor assessments.

AMA considers that the following foundational principles are not adequately reflected in the draft Code:

- **Proportionality:** control, formality, documentation and review must reflect risks to quality, safety, efficacy and availability.
- **Demonstrable risk justification:** new or expanded obligations require evidence of the problem and expected regulatory benefit.
- **Flexibility:** requirements must accommodate different products, technologies, production frequencies, facilities and contract manufacturing organisation (CMO) arrangements.
- **Clarity:** required outcomes and the evidence expected to demonstrate compliance must be clear.
- **Equivalent approaches:** scientifically justified alternatives should be accepted without an undefined presumption against them.
- **Accountability:** manufacturers, auditors and the regulator must support their positions through the same risk-based framework.
- **Continuity:** established systems with satisfactory compliance histories must be assessed through proportionate gap analysis rather than recreated.
- **Animal use reduction:** requirements must support validated alternatives to vertebrate testing and avoid additional animal use without a clear quality or safety benefit.

4. Terminology to improve regulatory clarity

Expressions such as ‘should’, ‘normally’, ‘unless otherwise justified’, ‘exceptional circumstances’ and ‘strong benefit-risk ratio’ require careful review. Manufacturers need certainty on whether a provision is mandatory, recommended or illustrative and how it will be applied in audits. Wording that appears to offer flexibility may instead establish an inflexible default, leaving the manufacturer to defend an alternative against an unstated baseline while providing no objective basis for an auditor’s decision.

AMA recommends replacing rigid default wording with an upfront requirement to assess and document relevant risks. The Code and guidance must identify assessment factors, expected evidence, escalation criteria and circumstances in which less formal approaches are appropriate. Both the proposed requirement and alternative approaches must be assessed against product and process risk, with the reasons for regulatory and audit decisions clearly articulated.

There are also consistency issues throughout the draft Code with the use of key instructions, such as ‘review’ versus ‘repeat’. Incorrect or inconsistent terminology changes the interpretation of a clause by both manufacturers and auditors. This is a critical issue that requires careful consideration throughout the draft Code.

5. Economic, operational and access impacts

The draft Code will increase recurring management and quality reviews, stability testing, stability chamber needs, validation and revalidation, environmental monitoring, audit preparation and remediation, documentation, record management and specialist training. The impact will be disproportionate for smaller companies, low-volume/small market products, multiple strengths, multiple pack sizes and products that may be manufactured only once or twice a year (or less). CMOs and contract laboratories are likely to pass additional costs to registrants via service fees. Potential consequences of these increased requirements include stock-keeping unit (SKU) rationalisation, withdrawal of niche products, reduced incentives for innovation and reduced attractiveness of local manufacture. These risks warrant assessment before finalisation.

6. Detailed comments on key issues

6.1 Product quality reviews (PQRs) — clauses 1.13–1.20

AMA supports periodic evaluation of product quality, but an annual, highly detailed review is not necessarily proportionate for every product or manufacturing model, especially when product was not manufactured in the assessment period. Flexibility for the manufacturer is required. Manufacturers should be able to set their own frequency for review and be able to justify their decision. Detailed guidance is needed for PQRs to clarify what constitutes a justified alternative to annual review frequency.

The PQR process is extensive, costly to conduct and will require investment in people to complete. The removal of low volume/small market products and rationalisation of SKUs is likely as companies seek to mitigate the impacts of increases in the overall cost of products.

Under clause 1.18, there may be unintended consequences arising from the way the clause is interpreted in relation to multinational companies, where many products are made offshore by the parent company but the registration holder is in Australia. As written, this clause could be interpreted to mean that PQRs from a sister site, under the same company, have to be evaluated and that the local Australian holder is accountable for ongoing management and review of actions. This represents a substantial duplication of effort with minimal value add.

The Code should permit PQRs for scientifically justified groupings (such as product family, dosage form, active substance, process, equipment or production line), rolling reviews using previous-period data where few batches are manufactured, and proportionate reviews when no batch is manufactured. Reviews completed at appropriately controlled international manufacturing sites or by CMOs must not be duplicated unnecessarily by the Australian registrant.

The TGA approach to PQRs[1] presents a more risk-based approach to PQR frequency. Although TGA states that PQRs are 'normally' conducted annually, it identifies three different pathways to producing PQRs – product-specific, product grouping and review by exception. This represents risk proportionality and flexibility where a statically invalid number of batches have been manufactured

[1] Performing product quality reviews (PQRs) for listed and complementary medicines | Therapeutic Goods Administration (TGA)

that year, so that PQRs may be done every two years, grouped with other similar products or through interrogation of the PQS and quality related events.

6.2 Quality risk management (QRM) — clauses 1.21–1.26

AMA supports documented quality risk management (QRM) where the depth, formality, documentation and review frequency is proportionate to risk. However a requirement to produce a written QRM report for every risk activity, approved by Quality and reviewed annually, is not proportionate or practical. A QRM should not be a one-size-fits-all approach – simple risks can be documented simply.

Some clauses in this section are unclear and expected to generate unintended consequences. For example, clause 1.21 states that risk reports are to be *reviewed* annually, with no sunset clause. This indicates that every risk report or risk-based decision must be reviewed on an annual, ongoing basis. If so, this places a burden on manufacturers that increases year on year.

The instruction to 'review annually' could easily be interpreted as 'repeat' annually. Reviewing and repeating a QRM report are very different tasks. For users, the language used is critical to provide necessary clarity and interpretation.

The Code should clarify which risk reports and risk-based decisions are intended to be reviewed annually and indefinitely, and avoid duplication between QRM, management review and PQR. Review triggers should include significant changes, adverse trends, deviations, complaints, recalls, new scientific information and changes in process knowledge.

6.3 Validation and Validation Master Plan — clauses 1.27–1.32

AMA supports risk-based validation requirements. Established qualification, operating history, maintenance, calibration, change control, deviation history and performance evidence must be recognised in documented legacy assessments. The Code must clearly and consistently distinguish between *reviewing* an existing risk assessment and *repeating* it (as in clause 1.28). A review *might* lead to the need to repeat, especially if something has changed, and the circumstances in which reassessment may be necessary need to be defined.

AMA anticipates greater use of external quality assessments in CMO validation and changes affecting registered products, with a high resource and cost impact for both registrants and CMOs, with likely increases in contracted service charges. Registrant oversight of outsourced validation must be risk-based, without routine duplication of CMO validation records.

6.4 Concurrent validation — clauses 7.101–7.102

Concurrent validation has been an established industry standard for decades and is used for process improvements, when moving products from one processing line to another, when batch sizes are increased, during a technology transfer from one facility to another, and during the introduction of a new formulation. Clauses 7.101-7.103 take a standard practice and make it very difficult to implement.

Each batch, prior to concurrent release, will have undergone the exact same rigorous testing and protocol controls as a prospective validation batch. The only difference is that the batch is released for commercial use before the entire multi-batch programme (i.e. three consecutive batches) is completed. Data from a single batch, with additional testing, provides a high level of assurance that the specific batch meets all quality attributes. Waiting for two more batch results will not change the quality or safety profile of the first batch.

An inability to perform concurrent validation will be a barrier and disincentive to process improvements, technology transfers and new product introductions. There are many niche products in the veterinary sector where only one or two batches are manufactured in a year, so requiring three validation batches will lead to expensive inventory carrying costs or product write-off. Financial losses are avoided where possible, so the inability to use concurrent validation will likely result in the loss of innovations and improvements, or be passed on to customers, thereby increasing the overall cost of animal health products.

Restricting the use of concurrent validation to undefined 'exceptional circumstances' involving a 'strong benefit-risk ratio for the treated animal' is subjective and creates uncertainty. A definition of 'strong' and/or a reference to an guidance document that is acceptable to APVMA would be very helpful here.

AMA recommends a defined, risk-based pathway where an approved protocol establishes critical process parameters and acceptance criteria, batch-specific testing is complete, deviations are investigated and the authorised person determines that the batch is suitable for release. Access to concurrent validation must not depend on an undefined comparison of the relative benefits of animal treatments.

6.5 Ongoing stability programmes — clauses 8.30–8.40

The addition of ongoing stability programmes is a major change and will create a substantial financial and operational burden on manufacturers and CMOs that is disproportionate to the benefit gained. Annual batch inclusion, multiple time points and coverage of each strength and primary packaging type, reference samples for two full sets of analytical controls and annual recall dummy runs will materially increase testing, laboratory workload, stability-chamber occupancy, record review and staffing requirements. These changes will require considerably more QC work to be done, by manufacturers and CMOs, and the limited capacity and availability of QC facilities and expertise in Australia must be taken into consideration.

Requiring one batch per year in every strength and every primary pack size significantly escalates the amount of quality control work that is required. Existing chambers have finite capacity and QC analysts have finite capacity, so this requirement will necessitate construction of new chambers, purchase of new lab equipment and recruitment of new staff. It will require considerable capital investment, facility space, qualification, temperature mapping, monitoring, maintenance, backup arrangements and additional operating expenditure.

The requirement to perform trend analysis also imposes considerable resource costs. Trend analysis requires a minimum of 4 time points per batch in order to generate a trend. Stability has usually been monitored by testing a batch at the end of shelf life (EOSL), which is one extra time point for the batch, and minimises overall testing requirements.

AMA expects that the new ongoing stability requirements will impose significant costs on both manufacturers and CMOs to enable compliance. Certain products will simply become too expensive to maintain on the market, resulting in various formulation strengths, pack sizes and niche products being deleted. This impact is multiplied when the burden of annual product reviews is also considered.

An ongoing stability programme should monitor products and enable the detection of stability issues. For legacy products with a good history of stability and low AER/PQC, adding one batch every single year is unlikely to provide new insights.

AMA recommends risk-based grouping, scientifically justified bracketing and matrixing, and reduced inclusion frequency where established stability knowledge, process capability, manufacturing and change history and complaint data support it. The Code should clearly address infrequent manufacture cycles and periods in which no batch is produced; recognise qualified outsourced programmes under technical agreements; and clarify trend-analysis expectations and minimum supporting data. Transition periods must accommodate chamber and laboratory expansion and training of new personnel. Where validated chemical, physical or microbiological methods support stability conclusions, the programme must not inadvertently generate additional routine animal testing.

AMA suggests that manufacturers be required to document a risk-based, ongoing stability programme that is justified around certain criteria, such as product category, similar products, worse case size, frequency of manufacture, AER/PQC history, mode of application, etc., and thereby support meaningful debate with APVMA auditors.

6.6 Computerised systems and data integrity

AMA supports appropriate controls for access, audit trails, electronic signatures, backup, incident management, system validation and record availability. Expectations must reflect its intended use and data criticality, with clear audit-trail review requirements and recognition of documented compensating controls for legacy systems. AMA notes that as drafted, the requirements for a system-generated audit trail (clause 6.11) for all GMP-relevant changes is stricter than the PIC/S (Annex 11) standard, and inconsistent with Annex 9 (clause A9-010) in the draft Code.

Registrants will require reliable access to relevant CMO records and assurance about significant incidents and changes – this should not require routine duplication or audit of the CMO's complete computerised-system quality file.

AMA anticipates that revisions to agreements, audit programmes and potential pass-through remediation costs will have high cost and resource impacts for companies, which will likely be higher for CMOs. A staged transition will be necessary, with a clear distinction between product-oversight information and the CMO's broader infrastructure controls.

6.7 Cleaning validation and cross-contamination

The Code must expressly recognise scientifically justified worst-case selection, grouping, bracketing and verification approaches. Registrants must have access to relevant worst-case rationale, validation conclusions, significant changes, deviations and product-impact assessments, without duplicating the

CMO's full programme where their products are covered by the control strategy. Documented QRM must determine an appropriate verification frequency and necessary controls.

6.8 Batch documentation, release, sampling and retention samples

Traceability and clear responsibility are essential. Quality agreements must specify ownership and storage of batch, testing and release records; links between sponsor and CMO records; ownership, location and storage conditions of reference and retention samples; access and testing rights; disposition decisions; and continuity if the relationship ends. Related records must be permitted to remain in validated source systems where protected and readily retrievable, avoiding unnecessary transcription or duplication. AMA considers batch documentation and release as a high-impact issue and anticipates increased External Quality review effort.

AMA recommends proportionate starting-material sampling where supplier assurance and validated controls are established, with clear method-validation expectations before extensive additional testing is required. Starting-material sampling, testing and method-validation arrangements need to be clarified by APVMA validation guidelines. Sampling and retention arrangements, plus storage and testing fees will increase costs, especially for CMOs. Guidance must support scientifically-justified reduced sampling, risk-based sample quantities and acceptable multi-site arrangements where the registrant and CMO hold different parts of the product record.

6.9 Contract manufacture and laboratory oversight

AMA supports risk-based oversight of contract manufacturing arrangements. The Code must distinguish registrant, contract-giver and contract-acceptor responsibilities and define thresholds for notification, review, approval and escalation of changes, deviations, investigations, out-of-specification results, recalls and validation activities. Agreements must address records, retention samples, stability studies, costs, regulatory communication and continuity of supply.

Audit frequency and scope must reflect the activity's risk and the contract acceptor's performance history, with reliance on qualified third-party evidence where appropriate. Oversight must establish suitability for the contracted activity without duplicating the entire CMO quality system. AMA expects that additional External Quality and Regulatory time will be needed to revise agreements, oversight plans and audit criteria, with high resource and cost impacts for both companies and CMOs. Duplicative review that adds no quality value must be avoided.

6.10 Animal testing and the 3Rs Principles

Expanded stability, batch-release and other testing expectations will increase animal use. This is inconsistent with APVMA's stated support of the 3Rs principles (to replace, reduce and refine animal use), and is also inconsistent with contemporary societal expectations. The Code must support replacement, reduction and refinement of animal use and expressly recognise validated alternative methods where they provide an appropriate basis for quality or safety decisions. AMA does not suggest that animal testing is never justified. Rather, each requirement must be carefully evaluated for meaningful additional assurance, the availability and acceptance of validated non-animal methods, and opportunities to reduce testing frequency through product knowledge, grouping, matrixing and risk-based lifecycle oversight.

6.11 Recall effectiveness checks

AMA expects a medium cost and resource impact from recall effectiveness checks, including sponsor-side traceability, distribution and regulatory coordination and participation in exercises involving CMO-manufactured products. AMA recommends that check frequency reflects distribution complexity, system changes, previous performance and actual recall experience, subject to an appropriate maximum interval.

6.12 Buildings and grounds — environmental monitoring

The draft Code elevates environmental monitoring of storage and processing zones to a fully managed validation programme. These programmes are generally not routinely revalidated and to do so will generate additional resource and cost impacts. AMA recommends that validation and revalidation expectations be explicitly risk-based and that transition arrangements recognise the work required to assess and adapt established environmental monitoring programmes.

6.13 Sterile manufacturing — Annex 1

Annex 1 requires clearer scope, risk-based frequencies and recognition of equivalent controls, particularly for heat-sterilisation revalidation, particulate limits, continuous environmental monitoring, processing hold times, simultaneous activities in closed systems and movement of sterilised components.

Continuous environmental monitoring will require two additional resources to implement trend monitoring. New requirements for Processing Hold Times and Validation will also require significant resourcing. Clauses A1-022 and A1-023 align the maximum permitted airborne particle concentration with **EN ISO 14644-1**. This represents a major shift from the 2007 GMO Code limits, particularly for the ≥ 5.0 μm particle size in Grade A and B zones.

Clause A1-080 is open to interpretation and onerous, which will lead to a significant reduction in the capacity of a sterile manufacturing plant. The term ‘re-validation’ has no definition, but if linked to the term ‘validation’, any ‘re-validation’ therefore needs to be performed again as per the original validation (IQ, OQ and PQ). The original validation PQ would include all equipment, validated three times with the full PQ suite of activities such as temperature maps, biological indicator maps and aseptic media trials (including sterile hold time). Under some manufacturing processes, sterile hold time that are validated may exceed 6 months, therefore an annual re-validation is not practical. There is no allowance in the clause as written to justify an alternative validation regime.

An alternative approach would be to require the manufacturer to document a risk-based approach to the ongoing re-validation of all sterilising equipment and processes. The manufacturer should be allowed to determine, and justify, the frequency for re-validation, taking into account factors such as process risk, the detectability of an adverse change, robustness of change control, automated versus manual cycles, deviations and representative worst case cycles. For example, sterilisation of a fermenter with nutrient media has a high level of detectability of change and is used multiple times a year, so an annual re-validation will not deliver superior outcomes. A risk-based approach can

determine the level of re-validation required, from review only, a single thermocouple map or single use of BIs, up to and including aseptic media trials.

Clause A1-120 will have negative unintended consequences as it does not take into account the use of closed system aseptic processing. For example, in a fermentation suite, non-sterile antigens will be in a state of manufacture at the same time as inactivated (i.e. sterile) antigens. Fermentation suites are governed under Annex 1. This clause will mean that multiple antigens cannot be handled in that room. In another example, the use of a closed system formulation suite where one batch of product may be being filled, another different batch in a different vessel may be having a pH adjustment, and a third batch in a different vessel may be having components added aseptically. These processes are performed in closed systems in the same room, which would not be permitted by this clause. The clause needs to be modified to allow different processing steps to be completed in the same room at the same time in a closed system environment with suitable segregation.

Clause A1-143 will also have unintended consequences by preventing the transit of sterilised containers, equipment or components through lower grades. Sterilised equipment, containers and container closure mechanisms are often sterilised outside of the clean room and wrapped or bagged in such a way to allow transport to the clean room through lower or ungraded areas. A common example is the use of gamma irradiation to sterilise containers and container closure systems. This is carried out offsite by a third party. The items are then transferred through an outdoor environment prior to reaching the site, but due to the unique bagging process, are transferred into A/B clean rooms with no issue.

Environmental monitoring must be designed and trended through documented risk assessment. Validated closed systems and suitable segregation must be recognised where they control contamination risk. Validated protective wrapping or equivalent controls must permit transfer of sterilised components through lower-grade or ungraded areas while preserving their status. Hold times must be scientifically justified and linked to product and process characteristics. AMA also requests clarification of applicable airborne particle limits, grades and operating states.

7. Unintended and cumulative impacts

The greatest burden of the draft GMP Code is anticipated to arise from the interaction of requirements within the Code and the wider regulatory framework, rather than any single clause. Management review, annual stability inclusion, trend analysis, validation and revalidation, environmental monitoring, CMO oversight and expanded record review may appear somewhat manageable alone but collectively, will require substantial additional staff, facilities, laboratory capacity, stability chamber space and audit time.

AMA considers that these cumulative risks are not insignificant, are not clearly justified by risk-analysis and will pose genuine risks to the ongoing availability of animal medicines in Australia. AMA requests that the APVMA considers these cumulative effects, taking account of product volumes, strengths and pack sizes, manufacturing frequency, reliance on contract manufacture, global supply chains, compliance history, specialist capacity, potential effects on smaller companies, niche product availability, barriers to innovation and local manufacturing capability, before finalising the GMP Code.

8. Implementation and transition

AMA expects that all supporting guidance will be published well in advance of implementation of a new GMP Code. The Guidance will be critical to interpreting the Code and to support mutual understanding of what is expected for compliance – for the APVMA, for the manufacturer and for the auditors. Further consultation is essential on both the Code *alongside* the new Guidance, and provide sufficient time for manufacturers to develop or adapt their processes. Industry input on the Guidance will be critical to ensure it is clear and practical.

AMA notes that the TGA has substantial guidance available for manufacturers, much of which may be useful as substrate for developing APVMA's guidance efficiently and without 're-inventing the wheel'.[2]

Established compliant systems and legacy equipment must be assessed through proportionate gap analysis, recognising qualified systems where no material change in risk has occurred. Requirements with potential implications for product availability must be identified early.

A staggered implementation of new GMP requirements would be welcomed by industry. Existing audit data could be used to identify the top three priorities for reform, where existing GMP requirements may require more timely update. Once these amendments are implemented, focus can shift to implementing the next set of priorities. The current process effectively seeks to update the entire GMP Code in one go, which imposes a substantial resource and cost burden at one time. Staggered implementation would enable a more proportionate approach to implementation, where the areas of demonstrated risk are prioritised and addressed first.

AMA also recommends a modular framework for structuring a new GMP Code. A modular Code would clearly identify the core GMP baseline requirements which every veterinary product must meet. Additional GMP modules would then be applied as relevant for sterile products, biologicals, injectables, antimicrobials, ectoparasiticides, feed products and others, according to their risks. This would preserve appropriate APVMA oversight, clarify expectations for the regulator, the manufacturer and the auditor, whilst avoiding controls that are irrelevant or disproportionate to a particular product or manufacturing activity. The Code would encompass the baseline requirements for all manufacturers and clearly identify the objective of each requirement. The Guidance would then provide the flexibility by explaining *how* a requirement could be satisfied in various ways, without being prescriptive.

9. Conclusion and priority recommendations

AMA supports an update of the APVMA GMP Code but considers that the draft Code requires considerable revision before finalisation. AMA's objective is not reduced quality oversight; AMA seeks a clearer, risk-proportionate and implementable framework that protects product quality while supporting availability, innovation, productivity and sustainable local manufacture.

AMA recommends that the APVMA:

1. Not finalise the draft Code in its current form.
2. Reassess significant new or recurring obligations against demonstrated risks and expected benefits.

[2] Guidance | Therapeutic Goods Administration (TGA)

3. Replace rigid default wording with upfront documented risk assessment and objective decision criteria.
4. Clearly separate mandatory baseline requirements from flexible guidance and examples.
5. Revise PQR, stability, validation, concurrent-validation and sterile-manufacturing provisions to recognise grouping, bracketing, matrixing, equivalent controls and risk-based frequencies.
6. Clarify registrant, manufacturer, CMO and laboratory responsibilities for validation, records, data integrity, stability and retention samples.
7. Explicitly recognise validated alternatives and respect the 3Rs principles where requirements may increase animal testing.
8. Assess cumulative impacts on smaller companies, niche products, CMOs, local manufacture and product availability.
9. Publish guidance well before implementation and consult on revised drafting and guidance.
10. Adopt staged or modular implementation with adequate transitions and proportionate treatment of established compliant systems.

AMA appreciates the opportunity to contribute to this review and supports further engagement to develop a practical, contemporary and risk-based GMP Code for Australian manufacturers.

Appendix 1. Priority drafting amendments

Draft provision	Concern and potential impact	Recommended amendment
1.13–1.20	Annual PQR and management reviews may impose disproportionate staff and audit costs, particularly for low-volume products.	Permit scientific grouping, rolling reviews, proportionate no-batch-year reviews and defined registrant–CMO responsibilities.
1.21–1.26	Duplicated and indefinite annual risk-report review may create documentation without added assurance.	Set proportionate documentation and defined review triggers, including changes in the risk profile.
1.27–1.32	Unclear reassessment and outsourced-validation expectations may duplicate work and increase service costs.	Recognise risk-based legacy assessments and proportionate access to relevant CMO validation evidence.
7.101–7.102	Undefined exceptions may impede concurrent validation, process improvement and niche manufacture.	Define a pathway based on approved protocols, batch controls, acceptance criteria and authorised release.
8.30–8.40	Annual inclusion and trending may increase testing and chamber demand, with potential SKU rationalisation.	Recognise grouping, bracketing, matrixing, reduced frequency, stability history and qualified outsourced programmes.
Annex 1, including A1-080	Annual revalidation may be read as extensive repetition of original validation, increasing capacity and resource burdens.	Define risk-based frequency and extent, including justified review-only and targeted verification approaches.
Annex 1, including A1-120 and A1-143	Restrictions may disrupt validated closed systems and protected transfers of sterilised components.	Recognise closed systems, suitable segregation and protective wrapping as equivalent contamination controls.
Chapters 6 and 9	Unclear boundaries between manufacturer oversight and CMO ownership may duplicate audits and records.	Define risk-based access, notification, data-integrity and quality-agreement responsibilities.
Chapters 4 and 7	Lack of express recognition of grouping and worst-case approaches may cause unnecessary cleaning validation.	Recognise scientific grouping, bracketing, worst-case selection and risk-based verification.