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Submission via email: ogtr.costrecovery@health.gov.au

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Dear Dr Bhula,

Consultation on the OGTR Cost Recovery Implementation Statement

Thank you for the opportunity to comment on the Office of the Gene Technology Regulator's (OGTR) proposed Cost Recovery Implementation Statement (CRIS) for 2026–27.

AMA is the peak industry body representing the leaders of the animal medicines industry in Australia. Our members are the innovators, manufacturers and registrants of a broad range of veterinary medicines that protect and treat animal illness, disease and injury, across the livestock, companion animal and equine sectors. AMA members represent approximately 80% of Australian sales of registered veterinary medicines.

Gene technology (GT) has the potential to contribute positively and significantly to animal health and welfare, agricultural productivity and sustainability, and Australian animal health companies are investing in this growing sector. AMA seeks to ensure that the OGTR is appropriately resourced to perform its statutory functions and a robust, science-based and risk-proportionate regulatory framework for gene technology.

1. Executive summary

The OGTR is widely regarded as a competent, responsive and trusted regulator. AMA member experiences note that the OGTR communicates effectively with applicants, makes decisions within statutory timeframes (or earlier) and imposes reasonable and proportionate licence conditions. The introduction of cost recovery should not undermine these strengths or alter the OGTR's approach to risk assessment and management.

AMA's support for in-principle cost recovery is qualified by concerns about the proposed timing, affordability and cumulative effect of the new fees. Phase 1 is proposed to commence on 1 March 2027, providing very limited time for organisations to adjust budgets, business cases, product-development plans and regulatory strategies. The changes will also occur alongside increased regulatory and compliance costs arising from major increases to Australian Pesticides and Veterinary Medicines Authority (APVMA) fees and higher compliance costs from the review of the APVMA Good Manufacturing Practice (GMP) Code. These concurrent financial changes are likely to adversely impact innovation and use of GT in the veterinary medicines sector, impede industry growth and sustainability, and deter investment in the sector in the future.

Additional costs to bring GT products to the Australian market are likely to disproportionately affect niche and specialised products, including products that address unmet health needs, conditions affecting relatively small populations or with intermittent market demand. Given the small market size, the commercial case for supplying a product in Australia may already be marginal. New fees could delay development or registration, affect investment decisions and contribute to products not being made available in Australia, even where they could offer significant public, animal or community health benefits.

AMA recommends that the OGTR consider the following amendments to the implementation plan:

- extend the transition period and provide applicants with at least 12 months' advance notice before Phase 1 rates are applied;
- consider staged fee increases over a longer period;
- establish exemptions, concessions or other safeguards for emergency uses, unmet health needs, niche products and products that are not commercially viable but would provide significant public or animal health benefits;
- provide greater clarity about the scope, timing and long-term direction of Phase 2;
- continue to support international consistency in regulatory definitions and approaches where appropriate;
- monitor the effects of the new arrangements on innovation, market access, regulatory performance and applicant relationships; and
- review and adjust the arrangements where evidence demonstrates adverse or unintended consequences.

AMA encourages the OGTR to retain its transparent and evidence-based approach while refining implementation arrangements to support innovation, regulatory access and the continued high performance of a trusted regulator.

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2. AMA's perspective

AMA's priority is to ensure that regulatory arrangements for veterinary medicines support safe and timely access to beneficial technologies while maintaining appropriate safeguards for human health, animal health and the environment.

Gene technology has the potential to positively contribute to animal health and welfare, agricultural productivity and sustainability, as well as to the development of vaccines, therapeutics and other health technologies. Australia's regulatory settings should facilitate access to these developments while preserving public confidence and ensuring that risks are identified and managed appropriately.

AMA does not oppose cost recovery in principle and supports the OGTR being adequately resourced to deliver high-quality assessments, decision-making and oversight. However, new fees should be designed and implemented carefully so that they do not create barriers to innovation, investment or the availability of beneficial products in Australia.

AMA has concerns that the government considers the GT sector to be 'mature' and therefore appropriate for cost recovery to commence. This assumption is not accurate with respect to veterinary medicines. While GT may be established for human medicine and in some sectors of plant science, it is **an emerging technology for veterinary medicines** and there is currently a limited number of registered GT veterinary medicines registered and marketed here. Of 232 DIRs listed in Australia, 15 are veterinary product licenses, of which only 4 are commercially available for use. Of 182 current DNIR licenses, there are approximately 12 of relevance to animal health.

GT techniques including gene editing, RNA vaccine platforms and breeding techniques offer great promise for veterinary medicine, but this is yet to be realised commercially. It does not seem appropriate that the government is seeking to recover costs from this emerging industry based on the incorrect assumption that all GT sectors in Australia are uniformly 'mature'. Adding cost recovery to the regulatory burden in the veterinary sector will discourage research investment and deter future GT investment and innovations from being brought to Australia.

3. Recognition of OGTR performance

AMA acknowledges the OGTR's strong reputation for timely and high-quality regulatory decisions. The OGTR is regarded by AMA members as being responsive to questions, accessible to applicants and straightforward to communicate with. Its decisions and licence conditions are considered reasonable and proportionate, and its statutory decision-making performance has been strong with 100% of regulatory decisions made within its legislated timeframes (if not earlier).

This performance is an important asset that should be protected during the transition to cost recovery. The cost recovery framework should support the continuation of OGTR's responsiveness, timeliness, risk-based approach and constructive relationships with applicants. It should not create incentives for unnecessary administrative complexity or delays.

4. Response to the CRIS

AMA commends the detail provided in the CRIS. It explains the activities undertaken for different application types and the factors affecting assessment time, regulatory effort and proposed charges for licence applications, certification applications and annual licence fees.

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The use of an Activity Based Costing methodology provides an evidence-based way to link fees to the resources required for regulatory activities. AMA supports the distinction between costs attributable to chargeable activities and broader regulatory functions that should continue to be funded through government appropriation. Applicants should not be charged for activities that are properly understood as broader public functions.

The proposed differentiation between high-complexity and low-complexity applications is appropriate. Recognising differences in regulatory effort is preferable to a uniform charge that could require less complex applications to subsidise more demanding assessments. Similarly, distinguishing between research, pre-commercial and commercial activities recognises that capacity to pay and public benefits may differ.

AMA particularly welcomes the inclusion of a Charging Risk Assessment (CRA) and risk mitigation measures in the CRIS. The CRA provides critical transparency for stakeholders and demonstrates that the OGTR has considered potential impacts and implementation risks of new cost recovery arrangements, especially for smaller organisations and research-focused entities, and to support Australian access to innovations.

5. Key concerns

5.1 Implementation timing

Phase 1 is scheduled to commence on 1 March 2027, representing a significant change from the longstanding position of zero application fees for OGTR activities. This timeframe provides limited opportunity for companies to evaluate investment decisions, product-development plans, regulatory strategies, budgets and internal approval processes within a changed regulatory environment.

The timing issue is particularly important for products already in development or projects whose commercial case was established on the basis of existing regulatory costs. Companies may have committed resources, entered agreements or developed market-access plans before the proposed charges were known. A new fee introduced late in the development cycle may be difficult to absorb and could affect whether a product proceeds to registration or not.

AMA therefore recommends a longer transition period, providing staged implementation and at least 12 months' advance notice of applicable fees. Applicants should be provided with sufficient time to evaluate the impact of any new fees on their regulatory plans, projects and budgets.

5.2 Cumulative regulatory costs

The impact of OGTR fees should not be considered in isolation. The veterinary pharmaceuticals sector is currently facing significantly increased APVMA fees and additional, ongoing compliance costs associated with the new GMP Code. These changes are expected to occur within a similar timeframe and are likely to affect the same product-development and market-access decisions.

The interaction between multiple regulatory cost changes should be recognised as an important implementation consideration. A fee that appears manageable when considered separately has a substantially greater effect when combined with other registration, manufacturing, quality, compliance and market-access costs.

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AMA data shows that approximately 80% of registered veterinary medicines return less than $1million in annual sales, and 50% of registered veterinary medicines return less than $200,000 per year. A novel GT product expected to return $200,000 in annual sales could reasonably be expected to incur the following costs:

- Overheads associated with product launch (marketing, labels, packaging, import fees etc): approx. $400,000
- APVMA application fee: approx. $350,000
- APVMA annual fee: approx. $750
- APVMA sales levy: approx. $860
- OGTR DIR license (high complexity) fee: approx. $44,070
- OGTR annual license: $3,710
- OGTR certification, high level containment fee: $5,420 (*NB: low level containment $160)*
- **TOTAL: $804,810**

Compliance with a new APVMA GMP Code (currently under consultation) will also add substantial ongoing compliance costs to maintain a veterinary medicine on the market. The estimated increase in compliance costs vary depending on product type, but have been estimated at $10,000-$50,000 per product at a minimum, and in some cases, hundreds of thousands of dollars per product.

AMA encourages the OGTR to engage with applicants and industry representatives to consider how these combined regulatory costs affect development pipelines, application timing, investment decisions and decisions to enter the Australian market. A phased implementation of OGTR fees would help companies manage these considerable costs to deliver benefits for animal health and welfare, human and environmental health, agricultural productivity and sustainability.

5.3 Annual licencing charge

AMA notes that the CRIS includes a proposed annual licence charge of $3,710.00, which will deliver an estimated revenue of more than $900,000. The justification for this fee is not clear, especially when compared to the annual registration renewal fee for APVMA of less than $1000. AMA acknowledges that ongoing regulatory activities generate costs for the regulator. However it is unclear why the annual fee for these services differs substantially between two key regulators (APVMA and OGTR) when the associated regulatory activities are arguably equivalent. The disparity suggests a flaw in the CRIS modelling or application of these fees by one or both regulators that should be clarified.

5.4 Niche and low-volume products

Higher regulatory costs are likely to have a disproportionate effect on products intended for small markets, specialised conditions, limited populations or periodic use patterns. These products may already face a challenging commercial case because expected sales volumes are low, development costs are high or demand is intermittent.

New fees could delay applications, limit proposed indications, affect product formulations or lead companies to exclude Australia from an international launch. Products addressing unmet health needs, responding to emergencies or providing important animal health and public health benefits may be particularly vulnerable where they are not commercially viable under ordinary market

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conditions. Emergency-use products and products required to respond to an outbreak or other urgent need may be particularly vulnerable to cost barriers.

AMA recommends that the OGTR consider whether the proposed fee structure provides sufficient flexibility for these circumstances. A transparent and clearly bounded exemption or concession framework would help ensure that cost recovery does not prevent consideration of products with significant animal health and welfare benefits, especially in emergency situations.

5.5 Innovation and access

The CRIS proposes that purely research-based licence applications will be exempt from application fees, while pre-commercial activities, including clinical and field trials, will be charged at 25% of the full assessment cost. Commercial applications will be charged at 50% of actual costs. These measures are intended to reduce the impact of cost recovery on early-stage research and some pre-commercial activities.

Nevertheless, fees may reduce the resources available for research and development, make investment proposals less attractive, increase the cost of trials or influence whether a company proceeds with an Australian application. AMA notes that the use of gene technology in veterinary medicines remains relatively new in Australia, with only a small number of products available to date. Veterinary products must also comply with GMP standards, creating an additional cost barrier that is not incurred with plant-related applications.

5.6 Emergency and public-interest activities

AMA recommends a framework for applications involving emergency uses, unmet health needs, niche products and animal populations or indications that may not be commercially viable, but provide significant health or welfare benefits. This could include:

- full or partial fee exemptions for emergency-use applications;
- reduced fees for low-volume or limited-use products; and
- phased or deferred payments where upfront costs would impede urgent access.

These measures would reduce or defer financial barriers without reducing the scientific, technical or safety requirements applied to a product. Where appropriate, emergency-use arrangements should align with APVMA emergency use permits and AUSVETPLAN response plans.

6. Recommendations

6.1 Transition to cost recovery

AMA suggests implementing the proposed 50% commercial licence charge through staged annual increases over five years, with increases of 10% each year to reach the intended 50% cost recovery over 5 years. A phased approach would provide companies with a more appropriate timeframe to incorporate new OGTR fees into development plans, budgets and business cases, while reducing the

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risk that projects already in development will be negatively affected by a large fee increase at a single point in time.

The transition should include clear milestones, public reporting and a commitment to review the approach if evidence shows that it is creating material barriers to innovation or access.

6.2 Transparency and future policy direction

AMA seeks greater clarity about Phase 2, which is anticipated from 1 March 2029 following legislative amendment to expand the range of OGTR activities subject to cost recovery. Stakeholders would welcome more information about the activities being considered for future cost recovery, the consultation and legislative process, the relationship with the proposed five-year review cycle, and whether the long-term objective is for partial or full cost recovery.

Clear information about the future direction of OGTR fees is important for investment and planning. Companies should be able to evaluate the impact of not only the Phase 1 fees, but also the likely regulatory cost environment over the life of a product or development program. Any further changes should be preceded by adequate consultation, impact assessment and notice.

6.3 International consistency

AMA recommends that the OGTR continue to support international alignment in regulatory definitions, evidence requirements and assessment approaches that are consistent with Australian health, safety and environmental obligations. Differences between Australian regulatory definitions of genetically modified organisms and those used by overseas regulators may create additional complexity for companies seeking global registrations.

Any Australia-specific regulatory requirements increase development costs, extend timelines and reduce the attractiveness of including Australia in global product-development programmes. Comparable terminology, recognition and sharing of relevant international data and cooperation with overseas regulators can reduce duplication, support timely access to products and make Australia more attractive for global product-development programmes.

6.4 Safeguards for regulatory performance

The effect of cost recovery should be monitored using measures that cover more than financial performance. Reporting should consider the quality, timeliness and accessibility of regulatory services provided by OGTR before and after the implementation of cost recovery arrangements.

The AMA supports the OGTR's intention to publish quarterly performance information after cost recovery commences, including information on statutory decision-making and processing efficiency. The introduction of fees should not reduce the quality of pre-application engagement or discourage applicants from seeking clarification, particularly where classification, complexity or eligibility for a regulatory pathway is uncertain.

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7. Conclusion

The AMA supports the OGTR being adequately resourced and recognises the value of a transparent, evidence-based cost recovery framework. However, the proposed introduction of fees represents a significant change for applicants and may create challenges for innovation, investment and access, particularly when combined with other regulatory and compliance costs. The risks may be greatest for niche, low-volume and specialised products, emergency-use applications, products addressing unmet needs and projects that are already in development.

AMA recommends that OGTR consider implementation over a longer transition period with staged fee increases, appropriate exemptions and concessions, greater clarity about Phase 2, the prioritisation of international harmonisation in the GT sector and ongoing monitoring to help to ensure that cost recovery supports the OGTR's regulatory functions without undermining access to beneficial gene technology products in Australia.

Please contact me if you would like any further information on the points raised in our submission.

Yours sincerely,

Dr Charmian Bennett

Director, Science and Regulatory Policy

Unsigned for electronic submission

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