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Department of Health and Aged Care
GPO Box 9848
CANBERRA ACT 2601

By email only: gene.technology.implementation@health.gov.au

Dear Sir/Madam,

Re: Proposed amendments to the Gene Technology Act 2000

Thank you for the opportunity to provide comment on the proposal (the Proposal) to amend the *Gene Technology Act 2000*.

Animal Medicines Australia (AMA) is the peak industry association representing the registrants and approval holders of veterinary medicines and animal health products in Australia. They are the local divisions of global innovators, manufacturers, formulators and registrants that supply essential veterinary medicines and animal health products that are critical to supporting Australia's $34 billion livestock industry and the $33 billion pet industry. Our members represent more than 90% of registered veterinary medicine sales in Australia.

AMA and its members have a long-standing commitment to an animal health industry that is responsible and sustainable. Our members' products are essential tools that can help meet economic, environmental and social challenges.

AMA member companies play a vital role in Australia's food production, agricultural trade and biosecurity preparedness, as well as ensuring the health and wellbeing of our pets, wildlife and competition animals. AMA members develop, register and supply innovative new medicines including vaccines and anti-infection medicines to prevent and control outbreaks of animal disease, as well as medicines and treatments that enable good health and wellbeing, and the production of food and fibre products that are safe for human consumption and use. Healthy animals are much less susceptible to disease and infection, and good animal health is essential to good animal welfare.

Ensuring access to animal health products is vital to maintaining not only the health and wellbeing of the animals in our care, but also Australia's rigorous biosecurity systems, public health and access to safe, nutritious, affordable food.

Animal Medicines Australia is pleased to provide the following comments on the proposed amendments to the *Gene Technology Act 2000*.

Chapter 1: Scope of Regulation

Proposed amendments to the definitions of 'deal with', 'gene technology' and 'genetically modified organism'

To date, interactions between AMA members and the Gene Technology Regulator have primarily concerned animal vaccines. Products developed using next-generation breeding techniques (NBTs) are, however, becoming increasingly important tools in veterinary medicine, just as they are in human medicine. In the future, innovative new veterinary medicines developed using NBTs may be registered for use in Australia, such as antisera, vector vaccines, antivirals, immunoglobulins and monoclonal antibodies.

AMA supports the regulation of NBTs and genetically modified organisms (GMOs) in a way that reflects a true level of risk and is based on reliable scientific evidence. We support a science-based regulatory system that allows new technologies to be used to improve animal health and welfare, and protect public health, while preventing unacceptable risks to the health of animals, people or the environment.

The justification for expanding the scope of GMO dealings under the proposed definition of 'deal with' to include storage and transport is unclear. Where existing approvals confirm that there is negligible risk to health and safety of people or the environment, it seems unnecessarily onerous to require additional authorisation for storage or transport by e.g. wholesalers or retailers. In particular, further clarity regarding storage or transport of animals treated with mRNA vaccines. AMA suggests that existing authorisations would adequately cover storage and transport of GMOs or products resulting from the use of a GMO (including animals treated with mRNA vaccines). If additional requirements for storage and transport facilities were considered necessary, these should be limited according to risk.

AMA is concerned that the proposed amendments to the definitions for 'gene technology' and 'genetically modified organism' outlined in the Proposal retain existing process-based approach to regulation. Under the proposed amendments, any organism produced using gene technology would be considered a GMO and does not take into consideration the final product's characteristics.

An outcomes-based approach would enable the regulatory environment to keep pace with innovative NBTs and ensure a risk-based approach that is aligned with international standards. Many NBT-derived products are genetically identical to, and thus indistinguishable from, the same products developed using conventional breeding methods. For example, selective breeding through successive generations has traditionally been used to promote certain genetic traits, such as polled (hornless) cattle or particular fleece types in sheep. NBTs can achieve the same end point (i.e. a cow that lacks horn buds) relatively quickly, and with a much greater level of precision and control by targeting only the specific genes associated with the desired trait.

When an organism derived using gene technology is equivalent in its characteristics to an organism derived from conventional breeding techniques, it is appropriate that it is regulated in an equivalent manner. The use of gene technology is not sufficient to determine the risk of a particular organism or product to human or animal health, safety or the environment – hence, a risk-based approach should be employed to facilitate exemptions from the regulatory scheme.

AMA notes that the Proposal specifically excludes human beings from the definition of a GMO in any circumstances. This exclusion does not appear, however, to also apply to animals receiving the same or similar therapeutic interventions. AMA is concerned that this discrepancy may be detrimental to public trust in the Regulator. For consistency, AMA recommends that animals receiving therapeutic applications equivalent to those used in humans be excluded from the definition of a GMO.

In 2022, the United States Food and Drug Administration (US FDA) determined that intentional genomic alteration (IGA) of animals that results in the equivalent genotype and phenotypic trait observed in conventionally bred animals does not raise safety concerns. Consequently, the US FDA does not consider these animals to be GMOs and authorisation prior to marketing is not required.

AMA recommends the adoption of a risk- and outcomes-based approach to regulation by the regulatory scheme, which aligns closely with international standards and the approach proposed recently by FSANZ's Proposal P1055 *Definitions for gene technology and new breeding techniques*.

A responsive, risk- and outcomes-based framework will help avoid the regulatory scheme being outpaced by innovation and support the development of innovative animal health products.

Chapter 2: Risks considered under the Scheme

Dealing with GMOs that may also be regulated under other regulatory schemes

The proposed mechanism outlined in Section 15A to address situations where GMO dealings fall under multiple regulatory schemes is broadly supported. Reducing regulatory duplication or overlap is critical for improving the efficiency of the regulatory scheme, providing better clarity for registrants and fostering innovation. The Proposal will provide additional clarity regarding the responsibilities of the OGTR and other regulators and ensure that risks are assessed and managed by the most appropriate regulatory body, while ensuring that all relevant risks are adequately assessed and regulated.

Nevertheless, consideration must be given to ensuring that regulatory gaps do not emerge or that the regulatory framework does not become unnecessarily or overly complex.

Chapter 3: Authorisation pathways

GMO Licenses and Permits

The proposed amendments to the consultation on Risk Assessment and Risk Management Plans (RARMPs) for license applications will assist in improving transparency in the regulatory process by facilitating targeted public consultation. The effectiveness of the proposed amendments, and any potential impacts on the quality of decisions or efficiency of the regulatory process, will be determined by how they are implemented in the associated Regulations.

AMA supports the proposal to remove the requirement for the Regulator to consult on dealings which involve using a GMO to manufacture therapeutic goods locally, to align with existing requirements for overseas manufacturing. Removing this requirement will prevent the public release of CCI and information deemed to be intellectual property (IP). AMA recommends alignment between protections relating to the public release of CCI applicable to 'therapeutic goods', generally restricted to human pharmaceuticals, and those afforded to veterinary pharmaceuticals, including vaccines and other therapies.

Further clarity is required regarding the term "novel" as referred to in the Proposal to outline whether the Regulator would consult with the public on a RARMP for a license application. Proposal states that a dealing proposed to the authorised by a GMO licence that is derived from "a GMO that displays a novel trait that occurs because of gene technology, section 49 of the amended GT Act will require the Regulator to publicly consult" on the application. The Bill does not, however, outline how the term "novel" will be defined and practically applied in this scenario.

The proposed provisions for dealing with GMO permits introduce standardised, rather than case-by-case provisions, with the aim of streamlining the authorisation process. This permit process would likely improve efficiencies for certain products, e.g. where gene editing has been employed and results in minor genomic modifications. However, this approach may not align with other domestic or international frameworks, which are more outcome-based, rather than process-based, as outlined previously. This may negatively impact Australia's competitiveness and ability to access and adopt innovative technologies and animal health solutions.

Notifiable dealings

The proposed risk-tiering framework and use of rules for notifiable dealings will provide the Regulator with greater ability to respond quickly and more flexibly to technological advancements and innovation.

Further detailed consultation is required with key stakeholders to ensure that the rules achieve this goal, while ensuring a science-based approach to determining risk and maintaining clarity for registrants.

AMA supports the proposal for GMO dealings associated with the commercial supply of registered veterinary vaccines to be authorised as a notifiable dealing. Animal health products are subject to rigorous regulatory requirements, administered by the Australian Pesticides and Veterinary Medicines Authority (APVMA). This includes consideration of risks to animal health, human health and the environment and covers the registration of products produced using gene technology.

AMA supports measures that streamline interactions and reduce duplicative regulation between the OGTR and APVMA. Regulatory duplication confers significant cost, time and uncertainty, thereby strongly discouraging innovation and investment in Australia and deferring the realisation of benefits for animal health and welfare, and agricultural productivity.

Veterinary products are highly specialised, defined-use products and are most appropriately regulated by APVMA as the primary authority. The APVMA has the required expertise to understand and assess the risks to people and the environment associated with the use of a veterinary product, and its registration process carefully considers these factors. There is no additional benefit conferred by the OGTR duplicating the assessment of human health and environmental risks associated with the use of veterinary products. AMA therefore supports the proposal that in the case of veterinary medicines, the APVMA be the responsible regulator, with the OGTR providing specialist advice as required.

AMA supports the proposal for certain research activities to be considered 'non-notifiable dealings.' Consideration of existing premises quarantine accreditation by the Department of Agriculture, Fisheries and Forestry (DAFF) would increase confidence for GMO dealings.

GMO Register

The proposal to expand the GMO Register allows for a broader range of minimal-risk dealings to be included on the Register, potentially improving flexibility and reducing regulatory burden. While dealings included on the Register are considered low-risk, however, they remain GMOs under the regulatory framework and, as such, require appropriate regulatory and stewardship oversight regarding potential risks to human and animal health and safety and the environment, as well as market and trade implications.

The proposed approach does not require stakeholder consultation before a GMO is placed on the Register. To avoid unintended consequences regarding market acceptance and compliance and ensure transparency, AMA recommends introducing a requirement for stakeholder input in the decision-making process.

Chapter 4: Compliance, monitoring and enforcement

AMA supports consistent and transparent compliance, monitoring and enforcement regulatory activities that enable the Regulator to ensure adherence to the legislation. Such activities must, however, also be proportionate to the nature and risk level of the violation.

Chapter 5: Certification and accreditation

Detailed guidance relating to transitional provisions and new requirements would be beneficial for stakeholders.

AMA supports the maintenance of indemnity arrangements for members of Institutional Biosafety Committees to safeguard individuals from potential liabilities. Clear guidance outlining requirements should be provided for clarity and consistency.

Chapter 6: Use and disclosure of information

The proposed amendments to handling of Confidential Commercial Information (CCI) aim to strike a balance between protecting the commercial value of CCI and maintaining public trust in the regulatory

process through greater transparency. Further clarity regarding the scope and practical implementation of the proposed amendments is required, to determine whether the proposed approach achieves this balance. For example, the draft Bill allows disclosure of CCI to other government bodies in certain circumstances, including in assisting with their duties. There is a risk that this could lead to unnecessary or excessive disclosure of sensitive information.

Additional clarity is similarly required regarding the scope of proposed data exclusivity provisions, which would apply in circumstances where a government agency requires as a "condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort."

Chapter 7: Minor, technical and consequential amendments

Scope and process proposed for rules made by the Regulator

The Regulator is ultimately best placed to utilise a risk-tiering approach to make rules for accreditation, certification and the transport, storage and disposal of GMOs. Transparency and targeted stakeholder consultation will be key to ensuring balanced implementation of the proposed process and maintaining trust.

Application of provisions in the Act as amended

The proposed amendments relating to authorisation pathways, such as reclassification to notifiable dealings, may present compliance challenges in the short-term. The provision of clear guidance for stakeholders will be key to support registrants and ensure that the proposed amendments are applied efficiently and fairly.

Comprehensive consultation relating to the association Regulations will also be critical to ensure clear, equitable application of the proposed amendments.

Chapter 8: Application, savings and transitional provisions

The reclassification of some dealings in the Act may provide challenges and place increased administrative burden on registrants. Further clarity regarding how the provisions outlined in the Proposal will be implemented via the associated Regulations will be key to the transition period.

AMA recommends the development of a detailed transition plan, including timelines and guidance to support stakeholders during the implementation of the revised Act, to streamline the transition process.

In Summary:

AMA supports:

- The proposal to remove the requirement for the Regulator to consult on dealings which involve using a GMO to manufacture therapeutic goods locally, to align with existing requirements for overseas manufacturing.
- The proposal for GMO dealings associated with the commercial supply of registered veterinary vaccines to be authorised as a notifiable dealing.
- The proposal that in the case of veterinary medicines, the APVMA be the responsible regulator, with the OGTR providing specialist advice as required.
- The proposal for certain research activities to be considered 'non-notifiable dealings.'
- Consistent and transparent compliance, monitoring and enforcement regulatory activities that enable the Regulator to ensure adherence to the legislation.
- The maintenance of indemnity arrangements for members of Institutional Biosafety Committees to safeguard individuals from potential liabilities. Clear guidance outlining requirements should be provided for clarity and consistency.

AMA recommends:

- The adoption of a risk- and outcomes-based approach to regulation by the regulatory scheme, which aligns closely with international standards and the approach proposed recently by FSANZ's Proposal P1055 *Definitions for gene technology and new breeding techniques*.
- That animals receiving therapeutic applications equivalent to those used in humans be excluded from the definition of a GMO.
- The introduction of a requirement for stakeholder input in the GMO Register decision-making process.
- Alignment between protections relating to the public release of CCI applicable to 'therapeutic goods', generally restricted to human pharmaceuticals, and those afforded to veterinary pharmaceuticals, including vaccines and other therapies.
- The introduction of a requirement for stakeholder input in the decision-making process regarding the GMO Register.
- The development of a detailed transition plan, including timelines and guidance to support stakeholders during the implementation of the revised Act, to streamline the transition process.

If we can provide further information at any time, please do not hesitate to contact me.

Yours Sincerely,

Dr Katie Asplin

Director, Animal Health Policy and Engagement