Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Consultation: Proposed changes to the regulation of medicinal maggots

Consultation paper

Version 1.0, November 2025

Confidentiality

All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

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Overview

The Therapeutic Goods Administration (TGA) seeks your feedback on proposed regulatory changes to ensure the legislation governing medicinal maggots is fit-for-purpose. Specifically, this consultation seeks feedback on the following proposals:

(1) a 2-year transitional licensing exemption from the operation of Part 3-3 of the *Therapeutic Goods Act 1989* (the Act) in relation to the manufacture of medicinal maggots (referred to in this paper as the Good Manufacturing Practice (GMP) exemption); and

(2) reclassification of medicinal maggots from Class 4 (high risk) to Class 2 (lower risk) biologicals.

The TGA wants to ensure the regulation of medicinal maggots is fit-for-purpose, supports manufacturers to maintain the uninterrupted supply of medicinal maggots, considers patients' need to access, while ensuring quality and safety of treatments. Your input is essential to help ensure the proposed changes are practical, effective, and aligned with industry needs.

Providing feedback

How you can share your feedback

We are seeking your views on the proposals in this consultation paper to ensure the changes proposed to the legislation are fit-for-purpose. Questions are presented in this paper, and we ask that you respond to all questions relevant to you and/or your organisation.

Please send your written submissions using the Citizen Space portal by **10 December 2025.**
If you have any questions about the submission, email TGA.Scientific@health.gov.au

Scope

This consultation seeks feedback on proposed amendments to the legislation relating to the domestic manufacture of medicinal maggots.

The consultation paper covers the following areas:

- Part 1: Background
- Part 2: Proposed changes
- Part 3: Next steps

The following topic is **not** within scope of this consultation:

- developing new product-specific standards.

The TGA may conduct further consultations to seek views on compiling industry standards and whether further changes are required to develop the regulatory framework for these products.

Why we are consulting

No medicinal maggot product is registered on the Australian Register of Therapeutic Goods (ARTG) to support current supply, and viable animal cells and tissues are currently specified to be Class 4 (highest risk) biologicals. Classifying medicinal maggots as Class 4 biologicals is not considered appropriate. When the biological framework was amended to classify viable animal cells and tissues as Class 4 biologicals it did not anticipate the risk profile of whole organisms such as medicinal maggots. The consideration at the time was xenotransplantation products, which are often genetically modified viable animal cells or tissues with a high viral safety transmission risk, that are transplanted into patients. The risk profile associated with the use of medicinal maggots is considered much lower than xenotransplantation products.

Now having considered whole organisms, such as maggots, we are proposing the transition of medicinal maggots to Class 2 biologicals (lower risk) to better match their risk profile and mechanism of therapeutic use.

In addition, it is proposed to introduce a temporary exemption from GMP requirements (Part 3-3 of the Act) for manufacturers of medicinal maggots. This is intended to balance the need for ongoing supply of a lower risk product with providing a clear expectation of manufacturers looking to supply approved medicinal maggots in the future.

As unapproved goods, supply must continue to utilise the unapproved product pathways such as the Special Access Scheme (**SAS**), clinical trial and Authorised Prescriber (**AP**) pathways to ensure the benefit-risk of use is appropriately considered and access for patients is maintained.

Part 1: Background

Maggot Debridement Therapy (MDT)

Healthcare professionals have long used maggot debridement therapy (MDT) as an adjunct treatment for chronic and non-healing wounds. The first documented use of medicinal maggots appears in the Old Testament[1].

When antibiotics were introduced the use of maggots in wound treatments started to decline, however high rates of antimicrobial resistance and chronic wounds have allowed for a resurgence of MDT in recent times[2]. Researchers and clinicians are now seeking access to medicinal maggots as a potentially life-or-limb saving treatment for a growing range of conditions, particularly as an alternative to surgical debridement in patients where surgery is not an option, or for wounds that are unresponsive or resistant to conventional therapies and approved treatments.

Medical grade maggots are derived from green bottle fly larvae (*Lucilia [Phaenicia] sericata)* or from Australian sheep blow flies (*Lucilia [Phaenicia] cuprina*) and are introduced into non-healing skin and soft-tissue wounds of a human. The primary mechanisms of action on non-healing wounds include debridement, disinfection, stimulation of healing and/or biofilm inhibition and eradication[3]. This debridement leaves the healthy tissue intact while removing

[1] Larval therapy from antiquity to the present day: mechanisms of action, clinical applications and future potential (Whitaker et al., 2007)

[2] Maggot debridement therapy: Utility in chronic wounds and a perspective beyond (Sig et al., 2018)

[3] Pharmacological properties of the medical maggot: A novel therapy overview (Yan et al., 2018)

necrotic wound tissue[4]. Maggots have demonstrated effective debridement for varying wound types including:

- diabetic foot ulcers[5]
- limb salvage therapy
- pressure ulcers
- venous stasis leg ulcers
- wound bed preparation prior to surgical closure
- other traumatic, infectious, and vascular wounds[6]

MDT is generally considered as a clinically accepted adjunct therapy for wound debridement where a specialist confirms standard therapy is failing.

International regulation of medicinal maggots

Despite the long history of use, regulatory and supply approaches differ between countries. Internationally, medicinal maggots are regulated as both medicines (Canada[7] and Europe[8]) and medical devices (US FDA)[9]. Medicinal maggots are regulated as medicines in the UK, Europe (product specific waiver) and Canada, where they are primarily supplied in to clinical trials or as unapproved goods under prescription. In the USA, it is noted that the FDA clearance is as a legacy device under their 510(k)[10] system, and therapeutic maggots are unclassified. There are currently no harmonised international standards for medicinal maggot manufacture and use.

Existing TGA regulation of medicinal maggots

Framework

In April 2017, the biologicals framework was amended to clarify that "*goods that comprise or contain live animal cells, tissues or organs*" are to be regulated as Class 4 biologicals under the Therapeutic Goods Regulations 1990 (the Regulations)[11]. The classification of Class 4 biologicals was intended to capture gene-modified cell therapies and xenotransplant products, such as encapsulated or genetically modified porcine islets. However, inadvertently, medicinal maggots (and other whole organisms) are captured by this definition and are thus currently subject to regulation as Class 4 biologicals.

[4] A systematic review of maggot debridement therapy for chronically infected wounds and ulcers (Sun et al., 2014)

[5] Identification and characterisation of different proteases in Lucilia sericata medicinal maggots involved in maggot debridement therapy - ScienceDirect (Valachova et al., 2014)

[6] Maggot therapy takes us back to the future of wound care: new and improved maggot therapy for the 21st century (Sherman., 2009)

[7] https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/activities/fact-sheets/questions-answers-regulation-medicinal-maggots-medicinal-leeches.html

[8] http://geb.uni-giessen.de/geb/volltexte/2017/12734/pdf/BaumannAndre_2017_04_25.pdf

[9] https://www.federalregister.gov/documents/2024/tranfer-of regulatory-responsibility-from-CDHR-to-CBER-Medical Maggots and Medicinal Leeches

[10] https://www.accessdata.fda.gov/cdrh_docs/pdf7/K072438.pdf

[11] Schedule 16, Therapeutic Goods Regulations 1990 - Federal Register of Legislation

As such, a high level of regulatory oversight would apply, such as clinical trial approval (CTA) requirements, substantial supporting data package to support ARTG entry and high evaluation fees.

Now having considered the most appropriate classification for medicinal maggots, we are proposing medicinal maggots to be Class 2 biologicals (lower risk), to better match the risk profile and therapeutic use of medicinal maggots.

GMP and facility licensing

GMP is essential in the production of therapeutic goods to guarantee the safety and quality of manufactured products. This is achieved through consistent manufacturing processes and rigorous quality control programs. In practice, this includes the implementation of an appropriate Quality Management System (QMS), training of personnel, the design and qualification of the facility and equipment, the controls on the raw material and consumables, the validation of the process and the Quality Control (QC) methods, and the inspection by relevant authorities.

The TGA requires GMP licensing for all domestic sites that manufacture therapeutic goods unless exempted. Exemptions from GMP licensing may be granted where reduced regulatory oversight is justified by the TGA, or where alternative facility standards, typically supported by independent accreditation, are in place.

Existing GMP exemptions from TGA licensing

Existing legislated GMP exemptions are available to the current domestic manufacturers of medicinal maggots but, based on current governance arrangements, are limited to where:

- the manufacture of medicinal maggots is for initial experimental use in human volunteers (Item 1, Schedule 7 to the Therapeutic Goods Regulations 1990 (the Regulations)).
- the manufacture of goods is by a medical practitioner specifically for a patient under the practitioners' care (Item 1, Schedule 8 to the Regulations).

MDT has a long history of use, therefore it cannot be considered as ‘initial experimental use in human volunteers”. Therefore, Item 1 Schedule 7 does not apply.

Item 1 of Schedule 8 to the Regulations provides that medical practitioners, dentists and other health care workers registered under a law of a State or Territory are exempt from manufacturing licence requirements (Part 3-3 of the Act), where the manufacture of the medicine is by ‘a medical practitioner or a dentist specifically for a patient under their care’. This exemption (relevantly) applies where the following elements are met:

- The medical practitioner manufactures the good themselves and is unlikely to apply where the practitioner is only responsible for the oversight of the manufacture by staff under their direction.
- The purpose of the manufacture by the medical practitioner is specifically for a patient under that medical practitioner’s care.

Item 1 of Schedule 8 does not apply where the medicine is not manufactured directly by the medical practitioner specifically for a patient under their care.

In summary, current GMP exemptions for domestic medicinal maggot manufacture are highly restricted, underscoring the need for a transitional GMP exemption to support manufacturers, patient access, and ongoing supply.

Supply as unapproved therapeutic goods

The TGA regulates products that meet the legal definition of a therapeutic good under the Act. These products generally need to seek pre-market approval and be included in the ARTG before they can be imported, exported or supplied in Australia. To be entered on the ARTG, the TGA requires evidence of safety, quality, and efficacy as well as the manufacturing facility holding a GMP licence.

Unapproved therapeutic goods that are not included on the ARTG, such as medicinal maggots, can only be accessed in limited circumstances by a health practitioner for a patient in their care. If a health practitioner decides an unapproved product is appropriate for their patient, they can apply to prescribe it via the SAS and AP pathways. A doctor can also advise if a clinical trial for an unapproved product might be suitable for their patient. Unapproved therapeutic goods have not been evaluated by the TGA for quality, safety or effectiveness.

Current manufacture and supply of medicinal maggots

None of the domestic maggot facilities in Australia currently hold a TGA GMP licence or are approved for supply. The sector is small with only a low level of medicinal maggots currently being supplied in and exported from Australia.

The manufacturing process for medicinal maggots involves aseptic processing, starting with the cultivation of flies in a controlled environment, collecting and disinfecting their eggs, incubating them aseptically, and packaging the hatched maggots. As such, stringent sterility measures are considered crucial throughout manufacture to ensure the safety and efficacy of the product. The development of a suitable regulatory framework for these products is crucial to ensure that medicinal maggot products are safe and fit for their intended purpose.

In conclusion, it is vital that action is taken to ensure medicinal maggots are appropriately classified and regulated in Australia. While the current biologicals framework offers flexibility for variation in use and manufacturing settings, amendments to the Regulations are proposed to deliver proportionate regulatory oversight and safeguard continued access to this important, lower risk therapy.

Part 2: Proposed changes

A. Reclassification of medicinal maggots

Features

The TGA proposes the following regulatory updates to the existing biologicals provisions:

- classification of medicinal maggots as Class 2 biologicals (amendment to Schedule 16 of the Regulations)

- the definition of Class 4 biologicals as "*goods that comprise or contain live animal cells, tissues or organs"* will be amended to add "except medicinal maggots" (or similar).
- define medicinal maggots for debridement as Class 2 biologicals.

Considerations

Table 1 below, provides an overview of the rationale for classifying medicinal maggots as Class 2 biologicals. This comparison demonstrates that Class 2 is an appropriate classification as it offers greater regulatory flexibility, aligns with the risk profile, and supports GMP licensing with tailored requirements for both commercial and hospital-based manufacture.

Table 1: Justification for classification of medicinal maggots as Class 2 biologicals

Aspect	Class 2 biologicals (proposed)
Manipulation Level	The manufacturing process does not directly relate to the definition of 'minimal manipulation' as it applies to human cells and tissues. However, the risks of the manufacturing process are similar to other current Class 2 biologicals, involving growth, harvesting, sterilisation and aseptic packaging of the maggots.
Intended Use	Use of medicinal maggots for wound debridement would arguably align with the definition of homologous use (same function in nature as being utilised in the patient setting).
Examples	Human tissues (ocular, skin and musculoskeletal tissues) where minimal processing (includes both bioburden reduction and aseptic processing) and used for homologous purposes (same function in donor and recipient).
Risk Profile	As for other Class 2 biologicals, the use of medicinal maggots is clinically considered a low risk, with a high benefit-risk when used for debridement.
Regulatory Requirements	Tailored requirements based on manufacturing risk and clinical use, with less onerous quality data requirements and minimal requirements for product- specific data to support an intended clinical use.
Evaluation Fees	Lower fees would apply, reflecting the reduced regulatory requirements.
GMP Licensing	GMP inspection and licensing in a manner commensurate with product risk.

To implement the classification of medicinal maggots as a Class 2 biological, an amendment to Schedule 16 to the Regulations is required, which defines Class 4 biologicals as "*goods that comprise or contain live animal cells, tissues or organs"*. It is proposed to add an exception for "medicinal maggots" (or similar). This change would likely result in medicinal maggots being classified as Class 2 biologicals, but it is proposed to further amend that Schedule to state that medicinal maggots are Class 2 biologicals, to remove any interpretative doubt. We seek input on whether there is a need to further define the maggots or restrict the clinical indication to debridement. For example, is there a need to more tightly define the term 'debridement' or include a list of contraindications.

It is proposed that no transition period be applied to the amendment to the instrument due to the requirements being lowered.

Finally, by default the Therapeutic Goods (Standard for Biologicals - Labelling requirements) (TGO 107) Order 2021 and Therapeutic Goods (Standards for Biologicals—General and Specific Requirements) (TGO 109) Order 2021 apply to medicinal maggots. Careful consideration should be given by Sponsors to the applicability of these standards for medicinal maggots. Note that TGO 109 sets out general requirements relating to all biologicals, in addition to specific requirements applying to human musculoskeletal tissue products, human cardiovascular tissue products, human ocular tissue products, human skin products and human amnion products. Feedback is also sought on the need for development of a product-specific standard, in addition to TGOs 107 and 109, to ensure the quality and safety of medicinal maggots.

Questions

1. Do you support the proposed classification of medicinal maggots as Class 2 biologicals to better reflect their risk profile and intended clinical use?
2. Is the proposed classification of medicinal maggots, removing them from the definition of Class 4 biologicals and adding them to the definition of Class 2 biologicals, an appropriate and sufficient change?
3. Should the reference to medicinal maggots be restricted solely to debridement therapy, or should the intended clinical use be left to the discretion of the treating clinician approving the supply?
4. Should the definition for medicinal maggots explicitly exclude or include other intended clinical uses or contraindications?
5. In addition to excluding medicinal maggots from the definition of Class 4 biologicals, is there a need to specifically define medicinal maggots as Class 2 biologicals, to ensure there is no uncertainty about their-classification?
6. What impact, if any, do you expect the reclassification would have on manufacturers of medicinal maggots, including any cost-related impacts?
7. Do you support the application of TGO 107 and TGO 109 to medicinal maggots? If not, please indicate which specific requirements you believe should not apply, and explain why.
8. Is there a need for the development of a product-specific standard to outline additional quality and safety requirements (in addition to TGO 107 and 109)?
9. Do you have any additional feedback or suggestions regarding the proposed change, or the medicinal maggot regulatory framework more broadly?

B. Transitional GMP exemption

Features

The TGA proposes to introduce a 2-year GMP exemption for medicinal maggots manufactured by:

i. a medical practitioner registered under a law of a State or Territory when employed by a public or private hospital or a public institution, or a person under the professional supervision of such a medical practitioner; or

ii. a suitably qualified person for the purpose of medicinal maggot manufacture; and

iii. for supply to another public or private hospital, another public institution, or a private institution within Australia for the purpose of treating a medical condition of a patient of the hospital or institution.

Considerations

This proposal covers a temporary exemption for manufacturers of medicinal maggots to hold a GMP licence. Supply must still occur under the unapproved pathway provisions, where reporting of adverse events to TGA is still mandatory and advertising restrictions apply.

The exemption opens the possibility of medicinal maggots being supplied through the AP provisions, instead of SAS. To access the AP pathway, a medical practitioner must obtain approval from the TGA and the Human Research Ethics Committee (HREC) or receive endorsement from a relevant specialist college if applicable. This approval allows the practitioner to access and legally supply a specified 'unapproved' therapeutic good (or class of such goods) to a defined group of patients with a particular medical condition. Under the AP arrangement, the practitioner is permitted to supply the product directly to patients under their immediate care, without the need for separate approvals for individual patients. However, the product must not be supplied to other practitioners for prescribing or administration purposes.

In the absence of a GMP licence or specific quality standards, there is a risk the quality and use of medicinal maggots will be inconsistent, and patients will not have sufficient confidence of the safety and quality of the products used. This risk must be considered as part of the clinical decision for use of medicinal maggots in a particular patient and circumstance, as applies to the supply of any unapproved goods. Where quality or safety concerns exist or are identified, the TGA can consider the development of minimal standards that must apply to all medicinal maggots. This would also provide patients and prescribers with more confidence in the use of these products.

It is proposed this GMP exemption will be in place for 2 years. This transitional exemption is to support the maturation of the sector, with an expectation that manufacturers will work towards a GMP licence during this time and a further extension to the exemption is unlikely to be supported.

Questions

10. Do you support the proposed GMP exemption for medicinal maggot manufacturers?
11. What impact, if any, do you expect the proposed transitional GMP exemption would have on your manufacturing facility?
12. Will the proposed 2-year GMP exemption provide sufficient time for manufacturers to achieve a GMP licence?
13. Do you consider this option appropriately balances the need for continued supply with public health and safety? Please provide the reasons why it does or does not.
14. Are the details of the proposed exemption appropriate? Specifically, are the persons permitted to manufacture appropriately and adequately described? If not, please provide feedback and suggestions to improve the exemption details.

Part 3: Next steps

We want to hear from you

Your feedback is important to help the TGA understand how these proposed changes are received by stakeholders. Your input will assist in identifying any critical issues that may need to be addressed in future regulatory reforms. Submissions are invited from:

- manufacturers, research entities, healthcare professionals, and other interested parties of medicinal maggots

You may choose to remain anonymous. If you provide personal information, it will be managed in accordance with the **Privacy Act 1988** and the **Australian Privacy Principles**. For more details, see the Department of Health, Disability, and Ageing privacy policy.

We may contact you for further input based on your submission. If you prefer not to be contacted, please let us know in your response.

How to provide feedback

Feedback can be provided using the online submission form at Citizen Space. Please ensure your submission clearly addresses any concerns, suggestions, or support for the proposed changes. If you have any questions about the submissions or the process, please email TGA.Scientific@health.gov.au.

Submissions are due by 11.59 on 10 December 2025.

What we will do with your feedback

Written submissions will help the Department refine the legislative changes outlined in this consultation paper. Your input is essential to building a comprehensive understanding of the potential impacts of these changes. We will carefully assess any regulatory burden in relation to the expected benefits.

After reviewing all feedback, the Department will advise the Government on updates to the legislation to support the proposed amendments.

Following the consultation period, the TGA will:

- review all submissions received
- consider stakeholder feedback in finalising the proposed amendments
- publish a summary of responses and the final decision on the TGA website

We appreciate your contribution and look forward to your insights.

Privacy collection notice

The Department is bound by the Australian Privacy Principles (APPs) under the Privacy Act 1988. These principles govern how we collect, use, store, and disclose personal information, and how individuals may access, or correct personal information held about them.

Providing personal information in your submission is voluntary. Please avoid including personal information about third parties.

Unless you request anonymity or confidentiality, the Department may publish your submission—including your name—on its website. If you do not request anonymity or confidentiality, you acknowledge that:

- your submission may be accessible to individuals outside Australia
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- you may not be able to seek redress under the Privacy Act if an overseas recipient mishandles your personal information.

The Department may redact parts of submissions before publication to remove defamatory, sensitive, or inappropriate content. Submissions containing offensive language or inappropriate material may not be published or responded to and may be destroyed.

Information provided in submissions, including personal information, may be shared with:

- the Commonwealth Government.
- state and territory governments, departments, and agencies.
- other third parties, where relevant to the consultation process.

For further information about how we handle personal information, please refer to the Department of Health and Aged Care Privacy Policy.

Consultation period

Stakeholders are encouraged to provide feedback on the proposed amendments to the regulatory framework. Table 1 outlines the key dates relevant to the consultation process.

Table 1: Key Consultation Dates

Action	Date
Consultation paper published and consultation commences	Mid Nov 2025
Consultation closes	Mid Dec 2025
Response published	Late Jan 2026

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Scientific Operations Management Section, Scientific Evaluation Branch	10/11/2025

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