Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'For official use only'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Pre-submission planning form

Category 1 and Category 2 applications

Refer to Information for applicants completing a pre-submission planning form when completing this form and in particular note prerequisites to be completed prior to submitting this form.

Notes:

- The *Pre-submission planning form* (PPF) and required attachments must be lodged with the TGA via eBS before the 1st of the month in which the PPF will be processed.
- A PPF is not required if the application is solely for the addition of new trade name/s.
- Information on data requirements, including minimum content, format, and condition of an application, is provided in CTD Module 1: Administrative information and prescribing information for Australia.
- Relevant technical guidelines (ICH, EU adopted in Australia and TGA guidelines) are available on the TGA website at <http://www.tga.gov.au>.
- When lodging the PPF, ensure any required data/documents are uploaded as attachments in eBS.
- Where the symbol ** is shown in the PPF, this indicates that the specified document **must** be uploaded as an attachment when the PPF is lodged.
- Ensure that the following, where required, have been lodged with the TGA prior to PPF lodgement and the relevant advice has been received from the TGA:
  - a notification of a proprietary ingredient for each new proprietary ingredient.
  - an application form to propose a new chemical name (AAN), biological name (ABN), and/or herbal name (AHN) for each new non-proprietary ingredient.
  - an application for orphan drug designation.
  - justification for a new fixed combination.
  - acceptance as a literature based submission.

For an application to be effective, the DMF/s, where required, must be received by the TGA **prior** to lodgement of the application.

Part 1 Applicant and product details

1.1 Applicant details

Applicant name	Maxx Pharma Pty Ltd
eBS client ID	s47G
Postal address	PO BOX 620 Collins St West Melbourne VIC 8007 Australia
Address for correspondence	PO BOX 620 Collins St West Melbourne VIC 8007 Australia

	Primary contact	Secondary contact
Contact person (for the pre-submission phase)	s22	s22
Position (e.g. regulatory affairs officer, agent)	Regulatory Manager s47G	Senior Regulatory Manager s47G
Telephone number	s22	s22
Mobile number (optional)	N/A	N/A
Facsimile number	N/A	N/A
Email address	s22 @s47G	s47G

Note: The *Therapeutic Goods Act 1989* (the Act) provides penalties for making statements that are false or misleading in a material particular in, or in connection with, an application for registration of therapeutic goods.

1.2 Product details

Medicinal product details

Single active ingredient ☒ Multiple active ingredients ☐ Multiple components ☐

Is the product:

- a biological substance Y ☐ N ☒
- sterile Y ☒ N ☐
- composed of a sterile active ingredient that is not subjected to further sterilisation during drug product manufacture. Y ☐ N ☒
- intended for single use. If Yes, and if the formulation includes an anti-microbial preservative, include a scientific justification for the inclusion of the preservative. Y ☒ N ☐
- a product of a fermentation process. Y ☐ N ☒
- multi-dose usage (note: this does not refer to multi-strength). Y ☐ N ☒
- supplied with a device. Y ☐ N ☒

If the product is supplied with a device, provide details below:

N/A

Product table

Record the details of all products (registered and new) affected by this application.

AUST R (if appl.)	Active ingredient(s)	Trade (proprietary) name(s)	Strength	Dosage form	Pack/container
New	Dexrazoxane	Cardioxane	s47		

Note: For more information see Information for applicants completing a pre-submission planning form. If more than eight, insert comment, 'see attached document' in the first row.

Nature of proposed application/s

Select all that apply, noting that there may be new registrations and variations.

Note: A PPF is **not required** if the application is solely for the **addition of new trade name/s.**

New registrations

Note: Applications for new registrations lodged under section 23 of the Act and to which regulation 16C applies. A new registration is one that requires a new ARTG entry by reason of being separate and distinct goods under section 16 of the Act. By the provisions in the Therapeutic Goods (Groups) Order 2001, not all new registrations will result in a new AUST R number being allocated if they are taken to be grouped.

☐ **new chemical/biological entity [A]**

☐ **new salt/ester/isomer/complex/derivative** of existing active ingredient having different safety or efficacy properties **[A]**

☐ **similar biological medicinal product [A]**

If a similar biological medicinal product, complete information on the reference medicinal product:

Reference product - active ingredient	Reference product – trade (proprietary) name
N/A	N/A

Is the reference product **registered in Australia**?	Y ☐	N ☐
Does the reference product have the same **form**, **strength,** and **route of administration**?	Y ☐	N ☐
Have additional **comparability studies** been conducted?	Y ☐	N ☐
Has the same INN/ABN as the reference product been requested?	Y ☐	N ☐
Has the protected information period for the innovator product under section 25A of the Act expired?	Y ☐	N ☐
If no, will it expire before the application (dossier) lodgement date identified in section 1.4?	Y ☐	N ☐

☐ new **fixed combination** medicine **[B]**

☒ **extension of indications [C]**

☐ new **generic** medicine **[D]**

If a new generic medicine, complete the information on the reference product.

Note: Where a salt/ester is different to the reference product, provide a scientifically-robust justification at 2.3 Justifications and further information to demonstrate that the safety and efficacy properties are unchanged.

Reference product - active ingredient	Reference product - dosage form	Reference product - trade (proprietary) name
N/A	N/A	N/A

Has the protected information period for the innovator product under section 25A of the Act expired? Y ☐ N ☐

If no, will it expire before the application (dossier) lodgement date identified in section 1.4? Y ☐ N ☐

Was an overseas reference product used for bioequivalence studies? Y ☐ N ☐

☐ new **dosage form [F]**

☐ change/increase in **patient group [F]**

☐ change in **dosage**, e.g. dosage amount, frequency of use or dose regimen **[F]**

☐ new **strength [F]**

☐ new **route of administration [F]**

☐ change in **formulation [G]**

☐ change in **container type** (disregarding container size) **[G]**

Variation to register entry

Note: Applications to vary a Register entry lodged under section 9D(3) of the Act and to which regulation 16D applies.

☐ variation to Register entry resulting in a change of product information requiring evaluation of clinical, nonclinical, or bioequivalence data **[J]**

☐ **other variation** (requiring evaluation of clinical, nonclinical, or bioequivalence data) **[H]**

Provide further detail or justification for proposed application/s types as required.

N/A

Proposed schedule

For new substances, proposed Schedule

1.3 Indication(s)

Proposed indication(s)

Is this an application for a new chemical/biological entity, new fixed combination, similar biological medicine or new generic medicine? Y ☐ N ☒

If yes, provide the proposed indication(s) below.

If no, is there a change to indication(s) included in the application? Y ☒ N ☐

If yes, provide the proposed indication(s) below.

CARDIOXANE is indicated for use in the prevention of cardiotoxicity caused by anthracycline use. CARDIOXANE is indicated for the treatment of anthracycline extravasation in adults.

Currently approved indication(s)

Provide currently approved indication(s) below. For a new generic medicine or a similar biological medicine, provide the approved indication(s) of the reference product in Australia.

In Australia, dexrazoxane has not been registered for the indication of anthracycline extravasation. However, DEXRAZOXANE-REACH (ARTG- 428034 dated 24 March 2025) has been approved for the following indication: DEXRAZOXANE-REACH is indicated for reducing the incidence and severity of cardiomyopathy associated with doxorubicin administration in women with metastatic breast cancer who have received a cumulative doxorubicin dose of 300 mg/m2 and who will continue to receive doxorubicin therapy to maintain tumour control.

1.4 Application planning

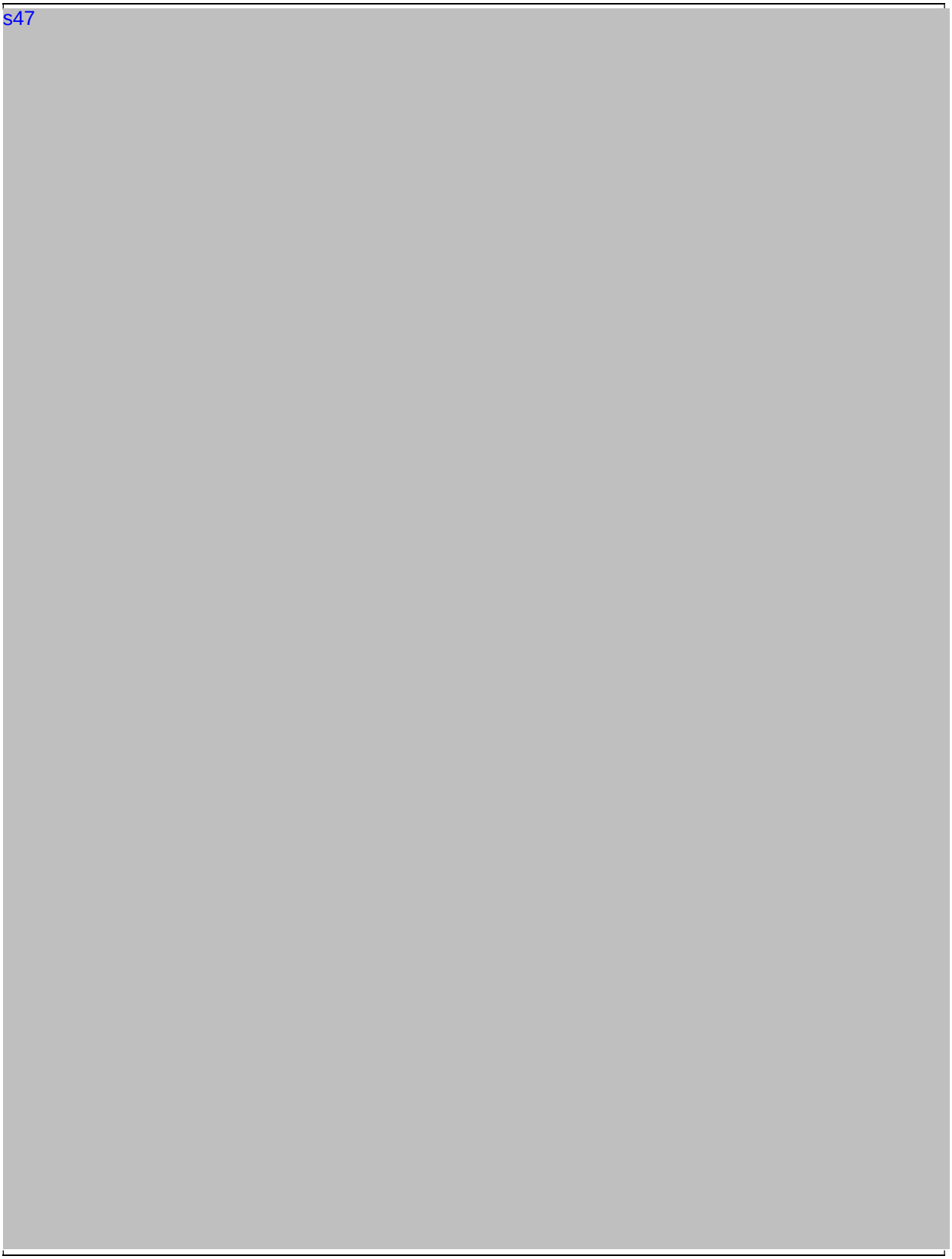
Overview of application

Provide a brief overview of the application. This includes (but is not limited to) a description of the product/proposed variation, and a succinct summary of the following:

- pivotal studies
- patient population.

Further information is provided in: Information for applicants completing a pre-submission planning form.

s47



Dossier lodgement date

Date on which the dossier will arrive at the TGA:	(dd/mm/yyyy) 31/10/2025

Related applications

If the application is related to any other application currently under evaluation by the TGA, provide relevant submission numbers.

Further information is provided in: Information for applicants completing a pre-submission planning form

Submission ID	Details of application
e.g. PM-2009-12345-1-1	e.g. Category 1 – extension of indication
N/A	N/A

Resubmission

Is this a resubmission? Y ☐ N ☒

If yes, provide the submission/pre-submission ID no. of the previous application.	N/A

Section 31 request response period

Nominated response time for the consolidated section 31 request for information:	30 calendar days ☐ 60 calendar days ☒

Part 2 Details of application

Note: Information on data requirements, including minimum content, format, and condition of an application, is provided in CTD Module 1: Administrative information and prescribing information for Australia. Relevant guidelines (ICH, EU adopted in Australia and TGA guidelines) are available on the TGA website at <http://www.tga.gov.au>.

Complete the following sections that are applicable to the application. When lodging the PPF upload any requested data/documents as unlocked attachments in PDF or Microsoft Office format.

Information provided with this PPF will be used for planning purposes prior to application lodgement.

****Indicates a document must be uploaded as an attachment when the PPF is lodged.**

2.1 General information

Section	Applicant checklist

Ingredients/proprietary ingredients

Note: All ingredient names must be approved by the TGA, or have an approval pending, prior to PPF lodgement.

Are there any new non-proprietary ingredients, or proprietary ingredients in the application? Y ☐ N ☒

If yes, ensure that the following have been lodged with the TGA prior to PPF lodgement:

- a notification of a proprietary ingredient for each new proprietary ingredient.
- an application form to propose a new chemical name (AAN), biological name (ABN), and/or herbal name (AHN) for each new non-proprietary ingredient.

**If forms for proposing a new chemical name (AAN), biological name (ABN), and/or herbal name (AHN) have been lodged with the TGA, attach copy/copies of the TGA's acknowledgement letter/s. Y ☐

Are any of the excipients used for purposes other than those purposes for which they are registered, for example, a new route of administration, or at an increased daily dose, or (for non-oral products) at an increased strength, compared with existing registered products? Y ☐ N ☒

If yes:

** Toxicology data will be provided to support the different usage. Attach an overview (Module 2.4) of additional supporting toxicology data to be provided to support the safety of the excipient for the intended purpose; OR Y ☐

Supporting toxicological data will not be provided in the application to support the different usage.

Provide an overview of the justification for its omission at *2.3 Justifications and further information*. Y ☐

Fixed combinations

Does this product contain a new fixed combination of active ingredients? Y ☐ N ☒

** If yes, attach a copy of the TGA's letter advising that the justification for the fixed combination is acceptable. Y ☐

2.2 CTD Modules 1–5

CTD module	Applicant checklist

1.1 Comprehensive table of contents

** Attach a draft comprehensive table of contents, in a text-based format, that includes as a minimum Modules 3, 4, & 5 (where applicable to the application type). Y ☒

Note: Refer to Information for applicants completing a pre-submission planning form for information to complete this section.

Note: Where a study has been previously submitted for evaluation by the TGA, the entry for that study in the draft comprehensive table of contents (CTD Module 1.1), must be clearly annotated with the previous TGA submission number.

1.3.1 Draft product information (PI)

Will the application result in a new or revised PI? Y ☒ N ☐

New PI

**Attach a draft PI document that states (as a minimum) the Australian: Y ☒

- proposed indication(s)
- dose form
- dose regimen
- patient population
- formulation.

Note: It is strongly recommended applicants provide with the PPF a draft PI document that has been prepared specifically for the Australian market. Applicants can provide the core data sheet, or a summary of product characteristics (Europe) or prescribing information (USA), as long as the data listed above represents the proposed Australian registered product.

Revision of an existing PI

**Attach a draft revised PI document, clearly highlighting the proposed changes applicable to this application.

Y ☐

s47

Genetically modified organisms

Does this product contain or consist of genetically modified organisms? Y ☐ N ☒

** If yes, attach a copy of any OGTR licence, acknowledgement of receipt, or other record of consent from OGTR. Y ☐

Is the product derived from a genetically modified organism that is manufactured in:

- Australia? Y ☐ N ☒
- Overseas? Y ☐ N ☒

**** If yes to Australia, attach a copy of any OGTR licence, acknowledgement of receipt, or other record of consent from OGTR or, a declaration of exemption.** **Y** ☐

1.6 DMF, PMF, and CEP

Indicate which of the following files, if any, the application will reference.

s47

Note: For an application to be effective, the DMF must be received by the TGA prior to lodgement of the application.

If TGA file number unknown, provide name of DMF holder and/or code or version number of DMF.

s47

Plasma master file (PMF) Y ☐

Has the PMF been approved by TGA? Y ☐ N ☐

Name of PMF	PMF TGA file number
N/A	N/A

CTD module	Applicant checklist

1.7 Good manufacturing practice

The *Therapeutic Goods Act 1989* requires GMP clearances/licences for sites involved in production of the medicine. See CTD Module 1, for legislative requirements.

Note: Requirements for GMP clearances, certifications, and manufacturing licence applications are available from the GMP section of the TGA website.

Will Module 3 form part of the application or does the application make reference to a previously submitted Module 3, DMF or PMF? Y ☒ N ☐

If yes, provide the following details for all proposed manufacturers.

Details of overseas manufacturers

Currently cleared	Clearance required	GMP clearance or certification tracking number#	Manufacturer name	Country	Expiry date (if current)
☒	☐	s47			
☒	☐				
☒	☐				
☒	☐				
☐	☐				
☐	☐				
☐	☐				
☐	☐				
☐	☐				

Applications must have been submitted (draft status is not acceptable).

**Indicates a document must be uploaded as an attachment when the PPF is lodged.

Details of Australian manufacturers			
Currently approved	Approval required	Licence or tracking number#	Manufacturer name
☐	☐	(MI-YYYY-LI-NNNNN-N)	
☐	☐		
☐	☐		
☐	☐		
☐	☐		
☐	☐		

Applications must have been submitted (draft status is not acceptable).

Note: If there is insufficient room, include further details in an attached document.

CTD module	Applicant checklist

1.8.1 Meetings

Has written pre-submission advice been sought from TGA? Y ☒ N ☐

Has a pre-submission meeting been held with the TGA regarding this application? Y ☐ N ☒

Note: A meeting includes meetings conducted in any format (i.e. face to face, teleconference or videoconference).

** If yes, attach relevant documents (for example, copies of correspondence, meeting minutes, action items) and, where relevant, how/when any issues will be addressed. Y ☒

1.10.1 Overseas regulatory status

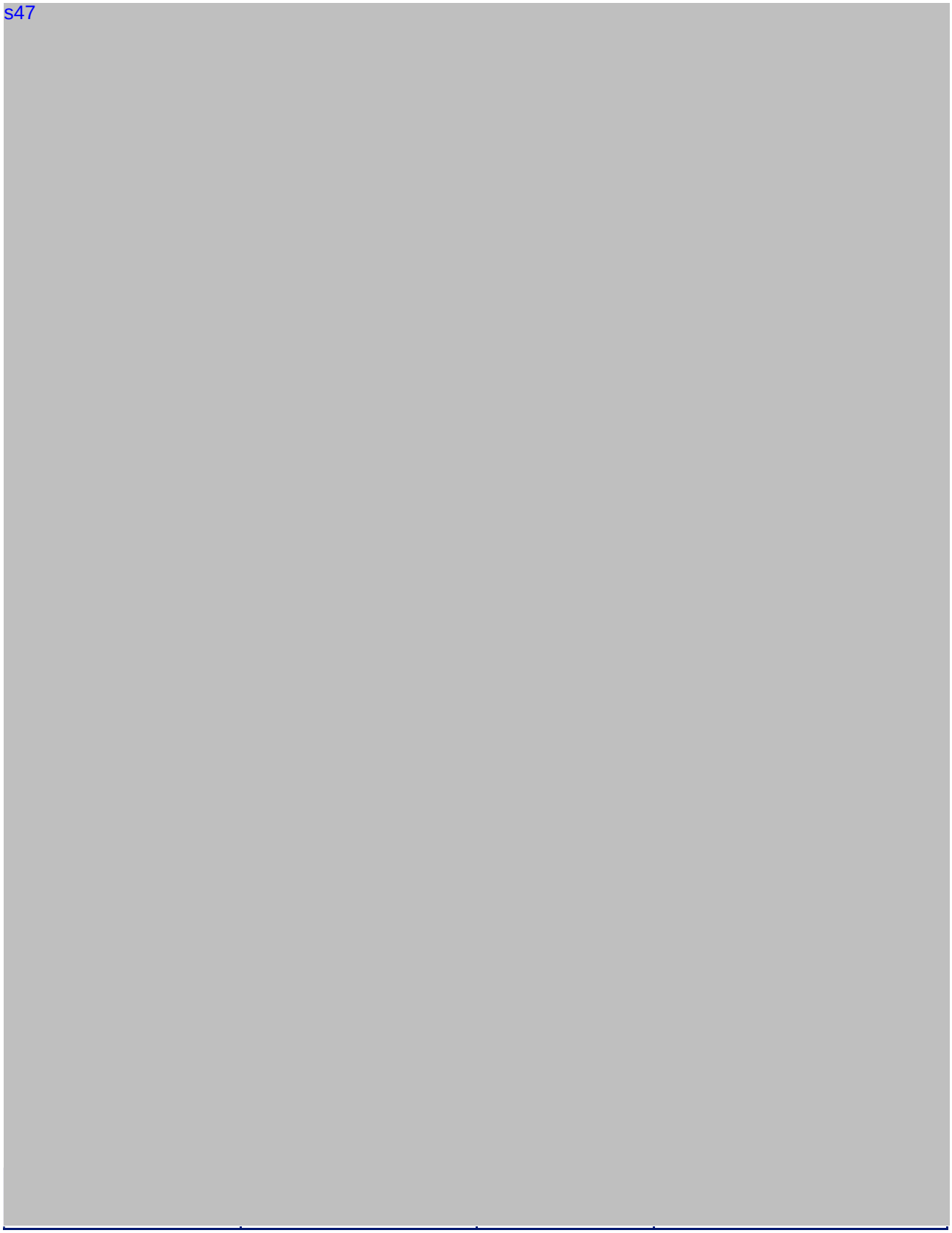
Has there been, or is there an intention to make similar applications for market approval in any of the following regions or countries? Y ☒ N ☐

If yes, indicate which countries.

Note: If insufficient room, include further details in an attached document.

Country/region	Date submitted or intend to submit	If approved	
		Approval date	Approved indications
s47			

s47



For all application types other than PI changes, has this application ever been refused market approval or withdrawn in any region or country? Y ☒ N ☐

If yes, provide details.

s47

CTD module	Applicant checklist

1.13 Pharmacovigilance

Will a risk management plan (RMP) be included in the application? Y ☒ N ☐

Note: Refer to the RMP guidelines to assess whether a RMP is required.

If no RMP is to be included, provide a justification below:

If yes, the current, unaltered EU-RMP (if available) and an Australian Specific Annex should be provided in the dossier. **Note:** An alternative to the EU RMP is acceptable only if there is no current EU-RMP.

CTD module	Applicant checklist

2 Summaries module

Will Module 2 form part of the application? (Note: Module 2 must be included with all applications under section 23 to which regulation 16C applies.) Y ☒ N ☐

Note: If yes, attach summaries (Module 2 documents or equivalent) of the proposed quality, nonclinical, and clinical evidence as described below. Equivalent documents may be provided; please refer to Information for applicants completing a pre-submission planning form for more details.

Note: Where an applicant believes the requirement for a document is 'not applicable' for a particular application, a justification must be included in section 2.3 Justifications and further information.

2.3 Quality

s47

2.4/2.6 Nonclinical

s47

2.5/2.7 Clinical

s47

s47

3 Quality module

Will Module 3 form part of the application or does the application make reference to a previously submitted Module 3, DMF or PMF? Y ☒ N/A ☐

If no, go to *CTD Module 4*.

If yes, complete the following sections.

3.2.S Drug substance

Manufacturer name	Address	Manufacturing steps
s47		

s47

Note: If insufficient space, include details in an attached document.

3.2.P Drug product

Manufacturer name	Address	Manufacturing steps
s47		

Note: If insufficient space, include details in an attached document.

Provide a description of the dosage form, including container and any delivery device that will be supplied with the product.

s47

Provide a description of the container closure system.

s47

CTD module	Applicant checklist

4 Nonclinical module

Will Module 4 form part of the application? Y ☒ N ☐

If no, go to *CTD Module 5.*

s47

4.3 Are literature references (CTD Module 4.3) to be included in the application?

s47

Note: For a description of what types of documents constitute literature references, see page 46 of ICH M4E Common technical document for the registration of pharmaceuticals for human use—efficacy.

5 Clinical module

Will Module 5 form part of the application? Y ☒ N ☐

If no, go to *2.3 Justifications and further information*.

Y ☒

5.2 ** Tabular listing of all clinical studies (CTD Module 5.2)

Note:

- a tabular listing of clinical studies must be attached if clinical studies are to be submitted;
- the table must include all clinical studies to be evaluated by the TGA, including biopharmaceutic studies;
- where the study has been previously evaluated by the TGA, the entry in the table for that study must be clearly annotated with the previous TGA submission number.

5.4 Literature references (CTD Module 5.4)

s47

Note: For a description of what types of documents constitute literature references, see page 46 of ICH M4E Common technical document for the registration of pharmaceuticals for human use—efficacy.

Justifications and further information

Justification for not providing biopharmaceutic and/or absolute bioavailability data

Note: "Justification" shall be considered to mean "the action to show that a thing is right, just or valid".

The guideline *Biopharmaceutic studies* and a number of EU guidelines that have been adopted by the TGA, establish the requirements for the generation and provision of biopharmaceutic data.

Where the application requires the provision of biopharmaceutic data but this data will not be provided, will not be provided for all products, relies on an overseas comparator (Choice of reference product for bioequivalence of generic medicine) or otherwise will not meet the requirements set out in the relevant documents and guidelines, a robust scientific justification (with references as appropriate) must be included in the application. Further, where multiple guidelines/requirements have not been met, each guideline/requirement must be addressed.

Provide an overview of the justification/s related to the biopharmaceutic data to be included in the application. If the justification/s is/are included in the Module 2 documentation, please provide details and reference to location/s.

s47

Justification for not meeting other guidelines

In relation to Modules 3, 4, and 5, if any other TGA-adopted or Australia-specific guidelines applicable to the application will not be fully met, robust scientific justification/s (with references as appropriate) must be included in the application to justify the reasons for not fully meeting these guidelines, including any anticipated critical omissions.

Provide an overview of the justification/s to be included in the application. If the justification/s is/are included in the Module 2 documentation, please provide details and reference to location/s.

s47

Tradename for release whilst submission is under evaluation (for Type A-C applications)

For new medicines or new uses for existing medicines that are currently under evaluation, the TGA publishes a summary of the proposed indication(s) and proposed tradename (as well as applicant name and active ingredient) https://www.tga.gov.au/resources/prescription-medicines-under-evaluation1. The list of medicines under evaluation is updated each month.

1 This page links to our database of applications for new medicines or new uses for xxisting medicines that are currently under evaluation by the TGA. The list of medicines under evaluation is updated each month. Information on three types of applications is included: Application type A: applications for a 'new medicine' containing a new active substance (new chemical entity or new biological entity) not currently approved in Australia. Application type B:

Please provide a Trade name for release on TGA's website whilst this application undergoes evaluation (published at https://www.tga.gov.au/resources/prescription-medicines-under-evaluation[2]).

Tradename: Cardioxane

Real world data (RWD), real world evidence (RWE) and patient reported outcomes (PROs) usage declaration (for all applications where applicable)

Please provide information on any RWD, RWE and/or PROs included in this submission and the reasons for their inclusion (e.g. claims supported by the data):

a. Details of location in eCTD of the RWE/PRO studies:

eCTD hyperlinks preferred:

b. Detail reasons for inclusion and the claims supported by the RWE/PRO data:

e.g. Safety in	*supported by data in Study*

Further information

Is there any other information in relation to this PPF that is relevant to the TGA's consideration of this document, or that might otherwise be relevant to the assessment by the TGA of the resources required for the evaluation of the application?

s47

applications for a 'new combination', where two or more already approved medicines are combined into a single product. Application type C: applications for a 'new indication', or additional therapeutic use, for an already approved medicine.

2 This page links to our database of applications for new medicines or new uses for xxisting medicines that are currently under evaluation by the TGA. The list of medicines under evaluation is updated each month. Information on three types of applications is included: Application type A: applications for a 'new medicine' containing a new active substance (new chemical entity or new biological entity) not currently approved in Australia. Application type B: applications for a 'new combination', where two or more already approved medicines are combined into a single product. Application type C: applications for a 'new indication', or additional therapeutic use, for an already approved medicine.

2.4 Summary of attachments

Note: This section identifies attachments the Applicant may be required to upload with this PPF and should be considered a reference guide/check list only. Refer to the Information for applicants completing a pre-submission planning form.

2.1 General information

- Copy or copies of the TGA's acknowledgement letter/s for lodgement of forms for proposing a new chemical name (AAN), biological name (ABN), and/or herbal name (AHN).
- An overview of additional supporting toxicology data to be provided to support the safety of an excipient for a different purpose.
- Copy of the TGA's letter advising that the justification for the fixed combination is acceptable.

2.2 CTD Modules 1-5

- Comprehensive table of contents, in a text-based format, for Modules 3, 4, & 5 (CTD 1.1).
- Draft document for a new or revised PI (CTD 1.3.1).
- For a LBS, copies of TGA's advice that:
  - the criteria for determining which of the papers identified by the search are to be included/excluded from the application are acceptable (CTD 1.5.1.1).
  - the literature search strategy is acceptable (CTD 1.5.1.2).
- Copy of TGA letter approving orphan drug designation (CTD 1.5.2).
- Copy of any OGTR licence, acknowledgement of receipt, or other record of consent from OGTR or, a declaration of exemption (CTD 1.5.3).
- Details of compliance with pre-submission meetings (CTD 1.8.1).
- Copy of the advice from the Office of Product Review stating that a risk management plan is not required (CTD 1.13).
- Summary of drug substance (CTD 2.3.S or equivalent).
- Summary of drug product (CTD 2.3.P or equivalent).
- Nonclinical Overview (CTD 2.4 or equivalent).
- Written Summaries of nonclinical data (CTD 2.6.2, 2.6.4, 2.6.6 or equivalent) or Tabulated Summaries of nonclinical data (CTD 2.6.3, 2.6.5, 2.6.7 or equivalent).
- Clinical Overview or equivalent (CTD 2.5).
- Clinical Summaries (CTD 2.7.1, 2.7.2, 2.7.3, 2.7.4 or equivalent).
- Either:
  - Draft synopses of clinical studies (CTD 2.7.6) OR
  - Synopses of pivotal phase III studies (minimum requirement).
- Tabular listing of clinical studies (draft CTD 5.2).

Part 3 Declaration

I acknowledge that the *Therapeutic Goods Act 1989* provides for offences and penalties for making statements that are false or misleading in a material particular in or in connection with an application for registration of therapeutic goods. ☒

I declare I have read Information for applicants completing a pre-submission form and completed this form in accordance with the instructions in that document. ☒

I declare that the information provided in this pre-submission planning form is, to the best of my knowledge, complete, current, and correct. ☒

I understand that, in order for the application to be effective:

a. I must provide to the TGA the complete application by the date specified in section 1.4, and that its contents must align with the information that I have provided in this form. ☒

b. the complete application must be prepared in accordance with any requirements of the Secretary under subsections 23(1) or (2), or subsection 9D(6) of the *Therapeutic Goods Act 1989* in relation to its form and the information to be provided and with the TGA's requirements as set out in Mandatory requirements for an effective application[3] acknowledging that selected information may not be required for my specific application or by approved exemptions. ☒

c. the dossier, as received by the TGA, will be considered to be the full and complete dossier, notwithstanding any further data requested by the TGA (including under section 31 of the Act) and/or new safety data, which I am obliged to bring to the TGA's attention. ☒

I understand that my application will be processed by the TGA in accordance with the procedures set out in Prescription medicine registration process.[4] ☒

I understand that, in accordance with the *Therapeutic Goods Act 1989*, if the application is not effective as defined under section 23 or section 9D(7) of the Act, my application will not be evaluated by the TGA. ☒

Name of authorised officer	s22
Position/relationship to applicant	Regulatory Manager (Agent to Maxx Pharma Pty Ltd)
Telephone number	s22
Facsimile number	N/A
Email address	s22 @s47G
Date	15 October 2025

[3] This document reflects requirements for an application to be considered effective under the *Therapeutic Goods Act 1989*. This document does not contain all the regulatory requirements for applications. Rather, it highlights a subset of requirements which applicants frequently overlook.
[4] This document explains the prescription medicine registration process and references regulatory and supporting documents.