Australian Government
Department of Health
Therapeutic Goods Administration

Changing a listed or assessed listed medicine

Application types and change tables

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TGA Health Safety Regulation

Contents

Introduction

Following the listing of a medicine in the Australian Register of Therapeutic Goods (ARTG), sponsors may need to make further applications to update certain product details. Some examples of changes that might be sought include formulation changes, changes to indications and changes to manufacturer details.

This guidance is for sponsors planning to change a listed or assessed listed medicine. It

- identifies the regulatory process you need to follow
- provides links to relevant guidance documents
- contains the Listed and Assessed Listed Medicines Change Tables, which is a tool to help you obtain essential regulatory information about change, including:
  - whether prior approval is required to make the change
  - the section of the *Therapeutic Goods Act 1989* (the Act) you are applying under
  - the application type (listed medicines) or application level (assessed listed medicines) for the change

This guidance applies only to medicines listed on the ARTG under sections

How to apply for a change

Applications to change existing listed and assessed listed medicines must be made via the listed medicine and assessed listed medicine forms in TGA Business Services (TBS) system.

Identifying all planned changes in the table

Before you make a change to your medicine, you will need to locate each planned change in the Change table so that you can:

- determine whether prior approval is required
- identify the change necessary (including consequential changes) to complete your application and determine the application type.

Ensure that you identify all changes that you intend to make, including changes that are consequential to the primary change.

Example: changing the maximum recommended daily dose (MRDD) on the ARTG entry may result in changes to the directions for use and medicine label.

Changing the MRDD when the medicine does not contain any ingredients that are restricted by the MRDD, is considered a C1 level change.

However, changing the directions is a C2 level change. Therefore, if the changing the MRDD also results in a change to the directions for use, a C2 level application will be required for both changes as L(A)C2 is higher than L(A)C1.

If you cannot find your proposed change in the Change Tables, contact us for assistance.

We have identified some of the common consequential changes and flagged them in the Change Tables, however please note this is not exhaustive.

Related information and guidance

- Listed and assessed listed medicines: Application and submission user guide
- Assessed listed medicines evidence guidelines
- General guidance for listed medicines
- CTD Module 1: Administrative information for assessed listed medicines

Changes under section 9D of the Act

To amend their ARTG entry, sponsors must make a request under the provisions of section 9D of the Act. The following requestions can be made under section 9D:

- **Subsection 9D(1)** allows sponsors to request an update to an ARTG entry that is incomplete or incorrect.
- **Subsection 9D(2)** allows sponsors to request safety-related variations to an ARTG entry. A variation is safety-related if it reduces the patient population, or has the effect of adding a warning or precaution.
- **Subsection 9D(3)** allows sponsors to request other variations to an ARTG entry where the change does not reduce the quality, safety or efficacy of the medicine.

Most section 9D variations will be made under subsection 9D(3) of the Act.

Correction to an ARTG entry (subsection 9D(1) requests)

A correction to an entry in the ARTG is generally a minor change to correct or complete information that was recorded incorrectly or omitted from the ARTG entry during the initial application to list the medicine.

Sponsors of listed and assessed listed medicines can request corrections to ARTG entries under paragraph 9D(1)(a) of the Act. Alternatively, the Secretary may make corrections to ARTG entries under paragraph 9D(1)(b) of the Act, at his or her initiative.

Examples of subsection 9D(1) corrections might include:

- Correcting errors in product name
- Correcting typographical errors in quantities of excipients
- Correcting ingredient names

For listed medicines, a request will only be considered if the current entry has omissions or mistakes that were made while listing the medicine. For Assessed listed medicines that are pre-market evaluated prior to their inclusion in the ARTG, some corrections could impact previous assessment(s) for listing or varying the medicine and may not be accepted as 9D(1) corrections. Contact us for assistance if you are unsure about a 9D(1) correction for an Assessed listed medicine.

When requesting a correction to the ARTG record, the change level shown in the Change Tables for that change does not need to be considered as the change code in Table F is used. For example, if an active ingredient for a listed medicine was not added to the ARTG entry at the time of listing, but was always included in the medicine and shown on the finished product specification at the time of listing, this may be approved as a subsection 9D(1) correction, despite that change being listed in the Change Tables as requiring an application for a new medicine with a new listing number.

You must submit:

- details of the correction or additional information to substantiate that a mistake was made
- relevant justification and documentary evidence that shows that the manufactured medicine has not changed. For example, a finished product specification that was signed and dated at the time of listing
- confirmation that the only changes being made to the ARTG entry are those identified in the request

A TGA delegate of the Secretary will review the request to assess whether the request is valid and adequate justification has been provided.

The current ARTG number (AUST L or AUST L(A) number) is maintained. A processing fee is payable for subsection 9D(1) requests.

Changes that create a separate and distinct good

Some changes may result in a listed or assessed listed medicine being treated as a separate and distinct good from the medicine currently included in the ARTG under subsection 16(1A) of the Act.

In these circumstances, the 'new' good must be separately entered in the ARTG and sponsors must apply to the TGA under s. 23 of the Act for approval of a new listed medicine.

Retaining an existing AUST L or AUST L(A) number

Depending on the nature of the change, the provisions of the Therapeutic Goods (Groups) Order No. 1 of 2001 ('the Groups Order') may allow the AUST L or AUST L(A) number of the existing medicine to be retained for the new medicine.

A 'grouping' is appropriate when the new medicine is intended to replace the currently supplied medicine, enabling the transition of one product to another.

Once the ARTG entry is changed, the new product automatically becomes active and the supply of the old product must cease.

New AUST L or AUST L(A) number

If a new listed or assessed listed medicine is separate and distinct from the existing medicine and the provisions of the Groups Order do not apply, you will need to submit an application to list a new medicine. For these applications, application type is indicated as 'New' in the Listed and Assessed Listed Medicines Change Tables. A separate application for a new medicine will be required.

- For listed medicines, this is automatically detected by the system on validation. A new and unique AUST L number will be issued.
- For assessed listed medicines, you will need to select an application type for a new medicine (L(A)1-L(A)3 application). Following evaluation, a new and unique AUST L(A) number will be issued. For further information on the appropriate application level for a new medicine, see the Assessed listed medicine guidelines.

If you do not intend to continue to supply the old product after approval of the new medicine, you will need to Request to cancel the ARTG entry for the old product. This will not occur automatically.

Fees

A summary of fees charged by the TGA for listed medicines and assessed listed medicines is available on the TGA website.

Changes to listed medicines

Application types

There are three application types for changes to listed medicines as described below.

Application type	Description
ARTG record update (ARTG)	Changes identified in the Change tables with the application level as **ARTG**. These include a minor change to a product's ARTG details generally to complete or update information in a non-mandatory field in the ARTG entry. No fee is payable.
Variation (Vary)	Changes identified in the Change tables with the application level as **Vary**. These include a minor change to a product's details that **does not** have the effect of creating a separate and distinct good under section 16 of the Act. The current AUST L number is maintained. A processing fee is payable.
Grouping (Group)	Changes identified in the Change tables with the application level as **Group**. These include a change to a product's details that has the effect of creating a separate and distinct good under section 16 of the Act **and** the Groups Order applies. A grouping application is only appropriate when the goods are intended to replace the currently supplied goods. The existing AUST L number is maintained. An application fee equivalent to a new product is payable.

Determining the application type for changes to listed medicines

When a change to the product record is made, the system will, upon validation, recognise the type of change made in accordance with the changes described in the Listed and Assessed Listed Medicines Change Tables.

If you are making more than one change to your medicine, the overall application type is determined by the change that attracts highest application level (ARTG Record Update being the lowest level and Grouping the highest).

Subsection 9D(1) requests

Some changes to listed medicines can be requested with a Correction to an ARTG entry in a single application.

- ARTG record updates and variations can be requested at the same time as a 9D(1) request.
- Grouping changes cannot be submitted at the same time as a 9D(1) request (unless the Grouping level change also meets the criteria for a correction to an ARTG entry.

Finalising your application

After an application is successfully submitted and the fees are processed, a computer program automatically makes the approval for the Secretary (except subsection 9D(1) requests).

After an application for a subsection 9D(1) request is successfully submitted and the fees are processed, a delegate will review the information provided and decide to correct the ARTG entry for the medicine.

- If approved, an acknowledgement email is then sent that informs the sponsor that a decision has been made to vary the medicine as requested.
- If the decision is not to vary the entry in the ARTG as requested, the decision letter will include both a statement of the reasons for the decision and information on your rights to appeal the decision. See Guidance for requesting reconsideration of an initial decision.

Changes to assessed listed medicines

Application types

Applications to change an ARTG entry for an assessed listed medicine are categorised into four levels as outlined below. Applications in lower levels require less supporting information, have lower fees and have reduced timeframes compared to applications in higher levels.

Application level	Description
Exemption update	Changes identified in the Change tables with the application level as **Fee exempt**. These changes are administrative and would not affect the established efficacy of the medicine. The TGA has determined that these changes pose a negligible risk. No fee is payable.
L(A)CN	Changes identified in the Change tables with the application level as **CN**. L(A)CN applications allow for changes where their implementation would not affect the established efficacy of the medicine. The TGA has determined that these changes pose a very low risk. Notifications include changes to the quality and non-quality aspects of a medicine and do not require assessment of efficacy data (or a justification for not providing such data).
L(A)C1	Changes identified in the Change Tables with the application level as **C1**. L(A)C1 applications include changes to the product label and ARTG entry that do not affect the efficacy of the product. C1 applications do not need efficacy data or a justification for not providing the data.
L(A)C2	Changes identified in the Change Tables with the application level as **C2**. L(A)C2 applications include changes that may affect the efficacy of the product. They require assessment of supporting efficacy data or a justification for not providing the data.

Determining the application level for changes to assessed listed medicines

Before you make a change to your medicine, you will need to locate each planned change in the Listed and Assessed Listed Medicines Change Tables and determine the application level. You will need this to complete your application. Ensure you identify **all** changes that you intend to make, including changes that are consequential to the primary change.

If you are making more than one change to your medicine, the application level is determined by the change that attracts highest application level (Exemption Update being the lowest level and L(A)C2 the highest).

Supportive documentation for assessed listed medicines changes

L(A)C1 and L(A)C2 applications

For most L(A)C1 and L(A)C2 applications you will need to submit supporting documentation. To determine the information necessary to support the change, you will need to identify and understand the relevant requirements outlined in the Assessed listed medicines evidence guidelines.

When compiling your dossier:

- follow Parts A to D of the General dossier requirements
- compile your dossier according to the Common Technical Document (CTD) format.

Your application dossier needs to identify all proposed changes and include relevant supporting information.

Ensure that your application cover letter includes the information described in the guidance on preparing a cover letter in CTD Module 1: Administrative information for assessed listed medicines.

L(A)CN and Exemption update applications

You do not need to provide a cover letter or submit a dossier for L(A)CN or Exemption update application, unless specified in the Change Tables.

L(A)CN and Exemption update applications may be reviewed to ensure they are valid notifications.

Where the change results in a change to the medicine label (refer to Table E of the Change Tables, the label should be attached to the application. Labels may be reviewed to ensure that the change is consistent with the changes outlined in the application.

Evaluating and requesting information

Evaluation of an application to change an assessed listed medicine will follow the application and approval processes outlined in the Assessed listed medicines evidence guidelines.

The TGA may request additional information under section 31 of the Act, about a proposed variation or to clarify information provided.

Requests processed as notifications (L(A)CN and Exemption update applications) are not evaluated.

Timeframes and fees for applications to change assessed listed medicines

Most applications for changes to assessed listed medicines attract an application fee. For certain applications a separate evaluation fee is also payable – refer to current fees.

Regulations 16GG and 16GH of the Regulations provide for legislated timeframes for applications to change assessed listed medicines. There are different timeframes for each of the application levels. While the TGA is required to complete the assessment within the specified timeframes, applicants should not implement the change until they are advised of the formal outcome of an application. The timeframes for evaluation of changes to assessed listed medicines are provided below.

Application level	Notification of acceptance of application (working days)	Evaluation timeframe (working days)
Exemption update	-	-
L(A)CN	-	N/A
L(A)C1	40	30
L(A)C2	40	120

Within 40 working days of receiving a valid application[1] for an L(A) C1 or C2 level application, the TGA delegate of the Secretary will notify the applicant in writing, whether the application has passed preliminary assessment.

After the applicant is notified that the application has been accepted, the TGA delegate will have an additional evaluation timeframe to make a final decision on the change. The legislated evaluation timeframe:

- commences once an application is accepted for evaluation and applicable evaluation fee has been paid
- applies to working days only and excludes public holidays and weekends
- excludes the time when the evaluation clock has stopped (for example: the time taken by the applicant to provide responses to formal requests for information; or when the applicant and TGA agree to a mutual stop clock).

Finalising your application

If the decision is to change the entry in the ARTG for your assessed listed medicine, you will receive the decision letter. For changes processed as notifications (L(A)CN and Exempt update applications), this decision letter will be generated once payment has been processed.

If the decision is not to vary the entry in the ARTG, the decision letter will include both:

- a statement of the reasons for the decision
- information on your rights to appeal the decision. See Guidance for requesting reconsideration of an initial decision.

[1] An application is considered 'valid' when it has been received by the TGA on the approved form and the relevant fees have been paid.

Listed and Assessed Listed Medicines Change Tables

Terminology used in the Change Tables

The following terms are used to describe changes include:

- **Change/Replacement**: This generally applies to changes made to existing information in a product's ARTG record. A change to an ingredient refers to a replacement of an ingredient with a different ingredient name, unless a certain characteristic of the ingredient has been identified (for example, ingredient quantity).
- **Update addition**: This generally applies when information is entered into a field that was previously empty. *Update addition* changes are generally due to system or legislative changes or where the sponsor is adding optional information. They also allow for changes to the rules, such as the addition of mandatory warning statements.
- **Update deletion**: Applies when there is a deletion of information from a non-mandatory field containing an unrestricted value.
- **Addition**: Applies when there is an addition of information to the product's record that is restricted or the change creates a separate and distinct good. For example, addition of an ingredient or export name.
- **Deletion**: Removal of information from the product ARTG record that is restricted or the change creates a separate and distinct good.

The *Change Tables* included in this document should not be considered an exhaustive list and will be updated by the TGA from time to time.

The tables refer to changes using the terminology that is consistent with the listed medicines and assessed listed medicine online application system.

For further information about listed and assessed listed medicines, refer to the Australian Regulatory Guidelines for Complementary Medicines (ARCGM) and the Assessed Listed Medicines Evidence Guidelines.

Some consequential changes have been noted in the change table. These notes should not be considered an exhaustive list.

Table A: Product detail changes

	Table A: Product details	Legislative basis	AUST L	AUST L(A)
Product name and product code				
A01	Change to product name.	23	Group	C1[2]
A02	Change to product name **AND** change, addition or deletion to indications.	N/A	New	New
A03	Change to product name **AND** any other change under section 23 (group).	N/A	New	New
A04	Change to the product code.	9D	ARTG	Fee exempt
Export name				
A05	Change, addition or deletion to export names.	23	Group	CN
A06	Change, addition or deletion to export names **AND** any other change under section 23 (group).	N/A	New	New
Composite pack				
A07	Change to medicine formulation name of a formulation in a composite pack.	9D	Vary	C1
A08	Addition or deletion of medicine formulation in a composite pack.	N/A	New	New
Medicine kit				
A09	Change, addition or deletion of a medicine from a medicine kit.	N/A	New	New

[2] Consider consequential changes to indications. Where the product name implies a therapeutic indication, the implied indication in the name would need to be included in and consistent with existing approved indications.

	Table A: Product details	Legislative basis	AUST L	AUST L(A)
Manufacturer				
A10	Change of manufacturer location.	9D	ARTG	Fee exempt
A11	Change, addition or deletion of manufacturer name.	9D	ARTG	Fee exempt
A12	Change, addition or deletion of manufacturer steps.	9D	ARTG	Fee exempt
Route of administration				
A13	Change, addition or deletion to the route of administration.	9D	Vary	C2
Dosage form and minimum weight				
A14	Change to the dosage form.	N/A	New	New
A15	Change or update addition to the minimum weight of divided dosage form quantity or unit when the formulation contains an ingredient **restricted** by concentration.	9D	ARTG	C1[3]
A16	Change, update addition or update deletion to the quantity or unit of the minimum weight of divided dosage form and the formulation **does not** contain an ingredient restricted by concentration.	9D	ARTG	C1[3]
Container				
A17	Change, update addition or update deletion to container type.	9D	ARTG	Fee exempt[4]
A18	Update addition or update deletion to the type of container closure, volume or volume unit.	9D	ARTG	Fee exempt[4]

[3] Consider consequential changes to ingredient quantities. See the Table B, Table C and Table D.

	Table A: Product details	Legislative basis	AUST L	AUST L(A)
A19	Change to the type of container closure, volume, volume unit.	9D	Vary	CN[4]
	Maximum recommended **single dose (MRSD)**			
A20	Change to the maximum recommended single dose (MRSD) quantity or unit when the formulation **contains** an ingredient restricted by MRSD.	N/A	New	New
A21	Change to the quantity or unit of MRSD when the formulation **does not contain** an ingredient restricted by MRSD.	9D	Vary	C1[5]
A22	Update addition or update deletion to the quantity or unit of the MSD when the formulation does not contain an ingredient restricted by MSD.	9D	ARTG	C1[6, 5]
A23	Update addition to the MSD quantity or unit when the formulation contains an ingredient restricted by MSD.	9D	ARTG	C1[6, 5]
	Maximum recommended daily dose (MRDD)			
A24	Change to the maximum recommended daily does (MRDD) quantity or unit when the formulation **contains** an ingredient **restricted** by MRDD.	N/A	New	New
A25	Change to the quantity or unit of the MRDD when the formulation does not contain an ingredient restricted by MRDD.	9D	Vary	C1[5]
A26	Update addition or update deletion to the quantity or unit of the MRDD when the	9D	ARTG	C1[5, 6]

[4] Consider consequential changes to label. For example, reformatting and resizing of text on label, pack size. See label changes in Table E.
[5] Consider consequential changes to directions for use and label. See the 'Directions for use' and label changes in Table E.
[6] An 'update addition' is only acceptable for assessed listed medicines when the information being included on the ARTG entry is consistent with previously approved details.

	Table A: Product details	Legislative basis	AUST L	AUST L(A)
	formulation **does not contain** an ingredient **restricted** by MRDD.			
A27	Update addition to the MRDD quantity or unit when the formulation **contains** an ingredient **restricted** by MRDD.	9D	ARTG	C1[5, 6,]
Indications				
A28	Change or addition of indications.	23	Group	C2[7]
A29	Deletion of indications.	23	Group	C1[7]
A30	Change, addition or deletion to indications **AND** change to product name.	N/A	New	New
A31	Change, addition or deletion to indications **AND** any other change under section 23 (group).	N/A	New	New
Warning				
A32	Change, update addition, addition or deletion of warning.	9D	ARTG	Fee exempt[8]

[7] Consider consequential changes to label. For example, addition/removal of indication to label, reformatting and resizing of text on label. See label changes in Table E.
[8] Consider consequential changes to label. See label changes in Table E.

Table B: Active ingredient formulation changes

	Table B: Active ingredient formulation details	Legislative basis	AUST L	AUST L(A)
General ingredient detail				
B01	Update addition to the ingredient quantity or ingredient unit when the ingredient type is AAN, ABN, AHN or AHS.	9D	ARTG	N/A
B02	Replacement, addition or deletion of an active ingredient.	N/A	New	New
B03	Change in the quantity or concentration of an active ingredient.	N/A	New	New
B04	Change to the final preparation ratio type when the ingredient type is AHN.	N/A	New	New
B05	Change to the equivalent quantity or unit when the ingredient type is AHN and the standardised component quantity has changed.	N/A	New	New
B06	Change to the equivalent preparation type when the ingredient type is AHN.	N/A	New	New
B07	Change to the ingredient quantity or units when the ingredient type is AHN and the component is standardised and the standardised component quantity has changed.	N/A	New	New
B08	Change to the final preparation ratio amount when the ingredient type is AHN.	N/A	New	New
Animal detail				
B09	Change or update addition to animal part, animal preparation or animal type.	9D	ARTG	Fee exempt
B10	Change or update to the country of origin for an ingredient of animal origin.	9D	ARTG	Fee exempt
B11	Change or update deletion to the Pre-clearance Number for an ingredient of animal origin.	9D	ARTG	Fee exempt

	Table B: Active ingredient formulation details	Legislative basis	AUST L	AUST L(A)
B12	Change to the 'Is this ingredient of human or animal origin' field when the ingredient type is an AAN.	9D	ARTG	Fee exempt
Carrier – AHN				
B13	Change to the carrier quantity or carrier unit when the carrier is restricted.	23	Group	C2
B14	Replacement, addition or deletion of a carrier when the ingredient type is an AHN.	N/A	New	New
B15	Change to the quantity of a non-restricted carrier.	9D	Vary	C2
Component				
B16	Update addition of a restricted component.	9D	ARTG	Fee exempt[9]
B17	Update addition to the field 'component standardised on this ingredient'.	9D	ARTG	Fee exempt[9]
B18	Update addition to the quantity or unit of a restricted component.	9D	ARTG	Fee exempt[9]
B19	Update addition to the quantity or quantity unit of a non-restricted mandatory component.	9D	ARTG	Fee exempt[9]
B20	Update addition of a mandatory unrestricted component.	9D	ARTG	Fee exempt[9]
B21	Change, addition or deletion of a standardised component of an active ingredient when the ingredient type is an AHN.	9D	ARTG	Fee exempt[10]

[9] Consider consequential changes to label and formulation. See all tables.

[10] Consider consequential changes to label and formulation. For example, change to plant preparation where there are no standardised components. See formulation changes in Table B and label changes in Table E.

	Table B: Active ingredient formulation details	Legislative basis	AUST L	AUST L(A)
B22	Change to the quantity or units of a standardised component when the ingredient type is an AHN.	N/A	New	New
B23	Change to the final preparation ratio amount or type when the ingredient type is an AHN, the component is not standardised and the equivalent preparation quantity has changed.	N/A	New	New
B24	Change to the equivalent quantity or unit when the ingredient is AHN and the component is not standardised.	N/A	New	New
B25	Change to the ingredient quantity or units when the ingredient type is an AHN, the component is not standardised and the equivalent preparation quantity has changed.	N/A	New	New
B26	Change to the component when the component is restricted.	9D	ARTG	C1[10]
B27	Change to the quantity or unit of a restricted component.	N/A	New	New
B28	Change to the final preparation ratio amount or type when the ingredient type is an AHN, the component is not standardised and the equivalent preparation quantity has not changed.	N/A	New	New
B29	Change to the ingredient quantity or unit when the ingredient type is an AHN, the component is not standardised and the equivalent preparation quantity has not changed.	N/A	New	New
B30	Change to the 'component standardised on this ingredient' field when the ingredient type is an AHN.	9D	Vary	C2
B31	Change to the quantity of an unrestricted mandatory component.	9D	Vary	C2
B32	Change to a mandatory unrestricted and non-standardised component.	9D	Vary	C2

	Table B: Active ingredient formulation details	Legislative basis	AUST L	AUST L(A)
B33	Change, update addition or update deletion to the component quantity or component unit when the component is unrestricted, non-mandatory and non-standardised.	9D	Vary	C2
B34	Change to the equivalent quantity or unit when the ingredient type is AHN and a component is standardised and the standardised component quantity has not changed.	9D	Vary	C2
B35	Change to the ingredient quantity or unit when the ingredient type is AHN and a component is standardised and the standardised component quantity has not changed.	9D	Vary	C2
Equivalent preparation – AHN or AHS				
B36	Update addition or update deletion to the equivalent preparation when the ingredient type is an AHN.	9D	ARTG	C2
B37	Update addition to the equivalent preparation when the ingredient type is an AHN and the equivalent is restricted.	9D	ARTG	C2
B38	Update addition or update deletion to the equivalent preparation type, equivalent quantity or equivalent unit when the ingredient type is an AHS.	9D	ARTG	C2
B39	Change to the equivalent preparation type, equivalent quantity or equivalent unit when the ingredient type is an AHS.	9D	Vary	C2
Homoeopathic preparation				
B40	Update addition to the potency of an active homoeopathic ingredient.	9D	ARTG	N/A
B41	Update addition to the ingredient quantity or ingredient unit when the ingredient role is active homoeopathic.	9D	ARTG	N/A

	Table B: Active ingredient formulation details	Legislative basis	AUST L	AUST L(A)
B42	Addition to the diluent quantity or unit of an active homoeopathic ingredient when the diluent is not restricted.	9D	ARTG	C2
B43	Update addition in the 'Label name' field of an active homoeopathic.	9D	ARTG	N/A
B44	Addition to the percentage of diluent of an active homoeopathic ingredient.	9D	ARTG	N/A
B45	Addition to the diluent quantity or diluent unit when the diluent is restricted and the ingredient role is active homoeopathic.	9D	ARTG	C2
B46	Update addition or update deletion to the equivalent preparation type, equivalent quantity or equivalent unit of an active homoeopathic when the ingredient type is an AHN or an AHS.	9D	ARTG	C2
B47	Update addition or update deletion in the field 'Diluent Not Present' when the role is active homoeopathic.	9D	ARTG	C2
B48	Change to the percentage of diluent of an active homoeopathic ingredient.	23	Group	C2
B49	Change to the diluent quantity or diluent unit when the diluent is restricted and the ingredient role is active homoeopathic.	23	Group	C2
B50	Change to the potency of an active homoeopathic ingredient.	N/A	New	New
B51	Change to the diluent quantity or unit of an active homoeopathic ingredient when the diluent is not restricted.	9D	Vary	C2
B52	Change in the 'Label name' field of an active homoeopathic.	9D	Vary	C1

	Table B: Active ingredient formulation details	Legislative basis	AUST L	AUST L(A)
B53	Change to the equivalent preparation type, equivalent quantity or equivalent unit of an active homoeopathic when the ingredient type is AHN or AHS.	9D	Vary	C2
Plant Part or Plant Preparation – AHN				
B54	Update addition to plant part or preparation when the ingredient type is an AHN.	9D	ARTG	N/A
B55	Change to plant part or preparation when the ingredient type is an AHN.	N/A	New	New
Solvent – AHN				
B56	Update addition of the percentage of solvent when the ingredient type is an AHN.	9D	ARTG	C2
B57	Update addition to the solvent residue quantity or solvent residue unit when the solvent is restricted and the ingredient type is an AHN.	9D	ARTG	C2
B58	Update addition of solvent residue when the solvent is restricted and the ingredient type is an AHN.	9D	ARTG	C2
B59	Update addition or update deletion to the solvent residue quantity or solvent residue unit when the solvent is unrestricted and the ingredient type is an AHN.	9D	ARTG	C2
B60	Change to the solvent residue quantity or solvent residue unit when the solvent is restricted and the ingredient type is an AHN.	23	Group	C2
B61	Change of a solvent when the ingredient type is an AHN.	N/A	New	New
B62	Change to the percentage of solvent when the ingredient type is an AHN.	N/A	New	New

	Table B: Active ingredient formulation details	Legislative basis	AUST L	AUST L(A)
B63	Change, addition or deletion of residual solvent when the solvent is not restricted and the ingredient is an AHN.	9D	Vary	C2
B64	Change to the solvent residue quantity or solvent residue unit when the solvent is not restricted and the ingredient type is an AHN.	9D	Vary	C2
Step in Preparation – AHN				
B65	Update addition of a step in preparation when the ingredient type is an AHN.	9D	ARTG	C2[11]
B66	Update addition to the preparation step ratio or preparation step ratio type when the ingredient type is an AHN.	9D	ARTG	C2
B67	Change or deletion of a step in preparation when the ingredient type is an AHN.	N/A	New	New
B68	Change to the preparation step ratio or preparation step ratio type when the ingredient type is an AHN.	9D	Vary	C2

[11] Consider consequential changes to final preparation ratio and solvent details. See Table B.

Table C: Excipient ingredient formulation changes

	Table C: Excipient ingredient formulation details	Legislative basis	AUST L	AUST L(A)
General ingredient detail				
C01	Replacement, addition or deletion of an excipient when the ingredient purpose is only as a colour, fragrance, flavouring, or printing ink.	23	Group[12]	C2[13]
C02	Change, addition or deletion of an excipient when the ingredient purpose is **not** as a colour, fragrance, flavouring, or printing ink.	N/A	New	New
C03	Change to the ingredient quantity or ingredient unit when the ingredient is restricted.	23	Group	C2
C04	Update addition or update deletion to the ingredient quantity or ingredient unit when the ingredient is unrestricted.	9D	ARTG	N/A
C05	Change to the ingredient quantity or ingredient unit when the ingredient is unrestricted.	9D	ARTG	C2
Animal detail				
C06	Change or update addition to animal part, animal preparation or animal type.	9D	ARTG	Fee exempt
C07	Change or update to the country of origin for animal part, animal preparation or animal type.	9D	ARTG	Fee exempt
C08	Change, addition or deletion to the Pre-clearance Number for an ingredient of animal origin.	9D	ARTG	Fee exempt

[12] There is currently a system limitation and in some circumstances this change needs to be processed manually by the TGA. When preparing an application, if it is not functioning correctly, a request should be made to Complementary.Medicines@health.gov.au.

[13] Where the combined changes to the quantity or concentration of the ingredient in the medicine differs from the original medicine by no more than 2% w/w or w/v of the formulation, the application is permitted as a C1 level change.

	Table C: Excipient ingredient formulation details	Legislative basis	AUST L	AUST L(A)
C09	Change to field 'Is this ingredient of human or animal origin' when the ingredient type is an AAN	9D	Vary	Fee exempt
Carrier – AHN				
C10	Change in the carrier quantity or carrier unit when the carrier is restricted and the ingredient type is an AHN.	23	Group	C2
C11	Replacement, addition or deletion of a carrier when the ingredient type is an AHN.	N/A	New	New
C12	Change to the quantity of an unrestricted carrier.	9D	Vary	C2
Component				
C13	Update addition of a restricted component.	9D	ARTG	Fee exempt[14]
C14	Update addition of a mandatory unrestricted component.	9D	ARTG	Fee exempt[14]
C15	Update addition to the component quantity or component unit when the component is restricted.	9D	ARTG	Fee exempt[14]
C16	Change to the component quantity or component unit when the component is restricted.	23	Group	C2
C17	Change, addition or deletion of an unrestricted non-mandatory component.	9D	Vary	C2
C18	Change, addition or update deletion to the quantity or unit of an unrestricted non-mandatory component.	9D	Vary	C2

[14] Consider consequential changes to label and formulation. See label changes in Table E and formulation changes in Table C.

	Table C: Excipient ingredient formulation details	Legislative basis	AUST L	AUST L(A)
C19	Change, update addition or update deletion to the quantity or unit of an unrestricted mandatory component.	9D	Vary	C2
Equivalent preparation – AHN, AHS or AFN				
C20	Change to the equivalent preparation type when the ingredient type is an AHN or an AFN, the ingredient is restricted and the ingredient purpose is only as a **colour, fragrance, flavouring, or printing ink**.	23	Group	C2[15]
C21	Change to the equivalent preparation type when the ingredient type is an AHN or an AFN and the ingredient purpose is **not** as a **colour, fragrance, flavouring, or printing ink**.	N/A	New	New
C22	Update addition or update deletion to the equivalent preparation and the equivalent is not restricted and the ingredient type is an AHN or AFN.	9D	Vary	C2
C23	Change to the equivalent quantity or equivalent unit when the equivalent is not restricted and the ingredient type is an AHN.	9D	Vary	C2
C24	Change, addition or update deletion of equivalent quantity or equivalent unit when the equivalent is not restricted and the ingredient type is an AFN.	9D	Vary	C2
C25	Change to the equivalent preparation type, equivalent quantity or equivalent unit the ingredient type is an AHS.	9D	Vary	C2
C26	Update addition to the equivalent preparation when the equivalent is restricted and the ingredient type is an AFN or an AHN.	9D	ARTG	C2

[15] Where the combined changes to the quantity or concentration of the ingredient in the medicine differs from the original medicine by no more than 2% w/w or w/v of the formulation, the application is permitted as a C1 level change.

	Table C: Excipient ingredient formulation details	Legislative basis	AUST L	AUST L(A)
C27	Update addition to the equivalent quantity or equivalent unit when the equivalent is restricted and the ingredient type is an AFN.	9D	ARTG	C2
C28	Update addition or update deletion to the equivalent preparation type, equivalent quantity or equivalent unit the ingredient type is an AHS.	9D	ARTG	C2
C29	Change to the equivalent quantity or equivalent unit when the equivalent is restricted and the ingredient type is an AHN or an AFN.	23	Group	C2
Plant part or Plant preparation – AHN or AFN				
C30	Addition to the plant part or plant preparation when the ingredient type is an AHN and the ingredient purpose is not as a colour fragrance, flavouring, or printing ink.	9D	ARTG	C2
C31	Addition to the plant part or plant preparation when the ingredient type is an AHN and the ingredient purpose is only as a colour, fragrance, flavouring, or printing ink.	9D	ARTG	C2[16]
C32	Change to the plant preparation when the ingredient type is an AFN and the ingredient purpose is only as a colour, fragrance, flavouring, or printing ink.	23	Group	C2[16]
C33	Change to the plant preparation when the ingredient type is an AFN and the ingredient purpose is not as a colour, flavouring, fragrance or printing ink.	N/A	New	New
C34	Change to the plant part or plant preparation when the ingredient type is an AHN and the ingredient purpose is only as a colour, fragrance, flavouring, or printing ink.	23	Group	C2[16]

[16] Where the combined changes to the quantity or concentration of the ingredient in the medicine differs from the original medicine by no more than 2% w/w or w/v of the formulation, the application is permitted as a C1 level change.

	Table C: Excipient ingredient formulation details	Legislative basis	AUST L	AUST L(A)
C35	Change to the plant part or plant preparation when the ingredient type is an AHN and the ingredient purpose is not as a colour, flavouring, fragrance or printing ink.	N/A	New	New
Solvent – AHN				
C36	Update addition of residual solvent when the solvent is restricted and the ingredient type is an AHN.	9D	ARTG	C2
C37	Update addition to the solvent percentage when the ingredient purpose is only as a colour, fragrance, flavouring, or printing ink and the ingredient type is an AHN.	9D	ARTG	C2[17]
C38	Update addition to the solvent residue quantity or solvent residue unit when the solvent is restricted and the ingredient type is an AHN.	9D	ARTG	C2
C39	Change or deletion of a solvent when the ingredient type is an AHN and the ingredient purpose is only as a colour, fragrance, flavouring, or printing ink.	23	Group	C2[17]
C40	Change or deletion of solvent details for ingredients that are not a colour, fragrance, flavouring, or printing ink.	N/A	New	New
C41	Change to the solvent percentage when the ingredient type is an AHN and the ingredient purpose is only as a colour, fragrance, flavouring, or printing ink.	23	Group	C2[17]
C42	Change to the solvent residue quantity or solvent residue unit when the solvent is restricted and the ingredient type is an AHN.	23	Group	C2

[17] Where the combined changes to the quantity or concentration of the ingredient in the medicine differs from the original medicine by no more than 2% w/w or w/v of the formulation, the application is permitted as a C1 level change.

	Table C: Excipient ingredient formulation details	Legislative basis	AUST L	AUST L(A)
C43	Change to the percentage of solvent when the ingredient type is an AHN and the ingredient purpose is not as a colour, fragrance, flavouring, or printing ink.	N/A	New	New
C44	Change, addition or deletion of residual solvent when the solvent is not restricted and the ingredient is an AHN.	9D	Vary	C2
Step in preparation or step ratio – AHN				
C45	Update addition of a step in the preparation of an AHN when the ingredient purpose is not as a colour, fragrance, flavouring, or printing ink.	9D	ARTG	C2
C46	Update addition of a step in the preparation of an AHN when the ingredient purpose is only as a colour, fragrance, flavouring, or printing ink.	9D	ARTG	C2[18]
C47	Update addition to the preparation step ratio or preparation step ratio type when the ingredient type is an AHN.	9D	ARTG	C2
C48	Change or deletion of a step in the preparation of an AHN when the ingredient purpose is **not** as a colour, fragrance, flavouring, or printing ink.	N/A	New	New
C49	Change or deletion of a step in the preparation of an AHN when the ingredient purpose is only as a colour, fragrance, flavouring, or printing ink.	23	Group	C2[18]
C50	Change to the preparation step ratio or preparation step ratio type when the ingredient type is an AHN.	9D	Vary	C2

[18] Where the combined changes to the quantity or concentration of the ingredient in the medicine differs from the original medicine by no more than 2% w/w or w/v of the formulation, the application is permitted as a C1 level change.

	Table C: Excipient ingredient formulation details	Legislative basis	AUST L	AUST L(A)
C51	Change or deletion of a step in the preparation of an AHN when the ingredient purpose is only as a colour, fragrance, flavouring, or printing ink.	23	Group	C2
Final preparation ratio – AHN or AFN				
C52	Change to the final preparation ratio amount or type when the ingredient type is an AHN and the ingredient purpose is only as a colour, fragrance, flavouring, or printing ink.	23	Group	C2[18]
C53	Change to the final preparation ratio amount or type when the ingredient type is an AHN and the ingredient purpose is not as a colour, fragrance, flavouring, or printing ink.	N/A	New	New
C54	Change to the final preparation ratio amount or type when the ingredient type is an AHN or an AFN.	N/A	New	New

Table D: Proprietary ingredient (PI) formulation changes

	Table D: Proprietary ingredient details	Legislative basis	AUST L	AUST L(A)
D01	Addition, deletion or replacement of PI name or PI identifier when the ingredient purpose is as a film coating, coating solutions cream base, oral base, empty capsule shell, preservative pre-mix, excipient pre-mix[19] or sweetener.	N/A	New	New
D02	Addition, deletion or replacement to the PI name or PI identifier when the purpose is **active pre-mix** or **active herbal extract**.[20]	N/A	New	New
D03	Addition, deletion or replacement of the PI name or PI identifier when the ingredient purpose is **only** as a colour, fragrance, flavouring, or printing ink.	23	Group	C2[21]
D04	Replacement of a PI with standard ingredients where there is no change to the formulation, ingredients or quantity[22].	9D	9D(1) request	C1
D05	Change or update addition to PI quantity or ingredient unit when the ingredient is restricted and the PI is not an active pre-mix.	23	Group	C2
D06	Update addition or update deletion to PI quantity or ingredient unit when the ingredient is not restricted and the PI is not an active pre-mix.	9D	ARTG	N/A
D07	Change to PI quantity or ingredient unit when the ingredient is not restricted and the PI is not an active pre-mix.	9D	Vary	C2

[19] For information on proprietary ingredient mixtures that do not clearly specify the purpose of the mixture see Streamlining proprietary ingredient categories.

[20] For information on proprietary ingredient mixtures that contain an active ingredient see Streamlining proprietary ingredient categories.

[21] Where the combined changes to the quantity or concentration of the proprietary ingredient in the medicine differs from the original medicine by 2% w/w or w/v or less of the formulation, the application is permitted as a C1 level change.

[22] The applicant must provide the formulation details for the proprietary ingredient that shows that the formulation has not changed since the medicine was listed.

Table E: Label changes for assessed listed medicines

	Table E: Label details	Legislative basis	AUST L	AUST L(A)
General				
E01	Reformatting or resizing of pre-existing text and movement of graphic. Addition of pack size, except where E02 applies.	9D	N/A	C1
E02	Change to sponsor details, including name and logo, except where F06 applies. Addition of pack size for dosage forms other than metered dose forms, where the new pack size falls within the approved pack size range and there is no change to the container type and packaging. Removal of pack size.	9D	N/A	CN
Indications, claims and graphics				
E03	Addition of pre-approved indications to product label.	9D	N/A	C1
E04	Re-wording of pre-approved indications on product label with same meaning and intent.	9D	N/A	C1
E05	Addition or change to graphics or marketing claims that relate to efficacy where supporting Module 5 data or a justification for not providing the supporting data is required (e.g. 'clinically proven', 'rapid action').	9D	N/A	C2
E06	Addition or change to graphics or marketing claims that relate to efficacy where supporting Module 5 data or a justification for not providing the supporting data is **not** required (e.g. consistent with existing approved indications and claims).	9D	N/A	C1
E07	Addition or change to graphics or marketing claims that **do not** relate to efficacy (e.g. general claims regarding the product, its nature, qualifying statements, 'new formulation', sponsorship of a campaign or organisation), except where F06 applies.	9D	N/A	C1

	Table E: Label details	Legislative basis	AUST L	AUST L(A)
E08	Removal of graphics or marketing claims that relate to efficacy.	9D	N/A	C1
E09	Removal of graphics or marketing claims that **do not** relate to efficacy, except where F06 applies.	9D	N/A	CN
Directions for use				
E10	Change to the directions for use.	9D	N/A	C2[23]
Warning statements				
E11	Change of advisory or warning statements.	9D	N/A	C1
Efficacy claimer				
E12	Change of location/size or addition of claimer of efficacy to the label.	9D	N/A	C1
E13	Removal of claimer of efficacy from the label.	9D	N/A	Fee exempt

[23] Consider consequential changes to the MRDD or MSD. See the 'Maximum daily dose' and 'Maximum single dose' sections of Table A.

Table F: Other changes

	Table F: Other details	Legislative basis	AUST L	AUST L(A)
F01	Correction of ARTG record in accordance with subsection 9D(1) of the Act. Evidence to support the change is included with the application.	9D	9D(1) Variation	C1
F02	Correction of ARTG record in accordance with subsection 9D(1) the Act. An application using this change code must include written advice from the TGA advising the use of this change code for the requested change to the product.	9D	N/A	Fee Exempt
F03	'Other' changes – application level CN. An 'other' code is used only when no other code applies. An application using F03 must include written advice from the TGA advising the use of this change code for the requested change to the product.	Specified in advice from TGA	N/A	CN
F04	'Other' changes – application level C1. An 'other' code is used only when no other code applies. An application using F04 must include written advice from the TGA advising the use of this change code for the requested change to the product.	Specified in advice from TGA	N/A	C1
F05	'Other' changes – application level C2. An 'other' code is used only when no other code applies. An application using F05 must include written advice from the TGA advising the use of this change code for the requested change to the product.	Specified in advice from TGA	N/A	C2
F06	The TGA does not need to be informed of changes to AUST L(A) medicine labels specified in change code F06 and no application is submitted if these are the only changes. Minor label editorials that have no regulatory compliance impact (under the Act). The changes are limited to the following: Correction of misspelt words and/or deletion of a duplicated word - this does not involve	-	N/A	-

	Table F: Other details	Legislative basis	AUST L	AUST L(A)
	rewording or the deletion of sentences or phrases. Removal of a 'new', 'new formulation' or a 'value pack' flash. Removal of details of sponsorship (in its entirety) of a campaign or organisation e.g. the Cancer Council's Pink Ribbon campaign. Deletion of sponsor logo provided the name and address of the sponsor or supplier of the goods are included on the label. Addition, removal or changes to: • country of origin statement (e.g. 'Made in XX') including the statement "Made in Australia" or "Australian Made" or the Australian Made logo (gold kangaroo in a green triangle) in accordance with the requirements outlined by the Australian Made Company (refer www.australianmade.com.au) • sponsor address and/or contact details provided the information is consistent with the current approved product details and where the name and address of the sponsor or supplier of the goods are included on the label • supplier or manufacturer's name, address and/or contact details provided the name and address of the sponsor or supplier of the goods is included on the label • date of manufacture of a product • website, QR code and/or bar code - applies only where the information included on the website (including any direct links from that website) or incorporated into the QR code or bar code (if either links to a website then any direct links from that website) is consistent with the information approved by TGA for that product • Australian Business name /Australian Company name • product code number (or equivalent) or an overseas registration number • recycle logo and associated text • tamper evident seal – wording/graphics			

	Table F: Other details	Legislative basis	AUST L	AUST L(A)
	• trade mark (™) or registration (®) symbols or similar, or trademark statements e.g. Company XXY is a registered trademark of Company XXZ Introduction, deletion or change of a graphic and/or text providing instruction on opening or closing a container. Anti-theft device (including directly associated wording) that does not impact on or affect the readability of other label wording.			

Glossary

AAN	Australian Approved Name, as defined in the TGA approved terminology for medicines
ABN	Approved Biological Name, as defined in the TGA approved terminology for medicines
Active ingredient	has the same meaning as in the Regulations
AFN	Approved Food Name, as defined in the TGA approved terminology for medicines
AHN	Approved Herbal Name, as defined in the TGA approved terminology for medicines
AHS	Approved Herbal Substance, as defined in the TGA approved terminology for medicines
AIN	Approved Ingredient Name, as defined in the TGA approved terminology for medicines
AUST L	General Listed Medicine including a single medicine or a composite pack listed under section 26A of the Act
AUST L(A)	Assessed Listed Medicine including a single medicine or a composite pack listed under section 26AE of the Act
Carrier	An excipient ingredient that is added to an active herbal preparation during processing of the raw herbal material
Claims	Statements about a product that do not describe a therapeutic use. For further information, refer to Permitted indications for listed medicines guidance or the Assessed listed medicines evidence guidelines
Component	A therapeutically active substance in an active ingredient. When the active ingredient is a herbal preparation, the component can be standardised or non-standardised to the active ingredient. Where the component is standardised to an active ingredient there must be compliance with the reference monograph or compositional guideline.
Equivalent preparation	The starting herbal material used to prepare a herbal preparation (e.g. extract or tincture). The equivalent preparation type is usually the fresh, dry or juice quantity used in a herbal preparation. This field is only applicable when entering AHN, AHS or AFN type ingredients
Excipient ingredient	has the same meaning as in the Regulations
HCN	Herbal Component Name, as defined in the TGA approved terminology for medicines
Indications	has the same meaning as in the Regulations. Claims and indications are mistakenly used interchangeably. This includes permitted, standard, specific and intermediate indications.

Maximum Recommended Daily Dose (MRDD)	The total dose recommended to be taken in one day. The MRDD is required if the formulation contains ingredients that are restricted by the daily dose.
Maximum Recommended Single Dose (MSD)	The quantity of a single dose recommended be taken at one time. MRSD is required if the formulation contains ingredients that are restricted by a single dose.
Proprietary Ingredient (PI)	Pre-mixed ingredient formulation, that the TGA has allocated a PI number (identifier), that perform certain functions, such as colour, film coating, or an empty capsule shell.

Version history

Version	Description of change	Author	Effective date
V1.0	Original Publication	OCM	1/8/2008
V1.1	Added new changes for product name, indications and MDD/ MSD changes	OCM	30/7/2012
V2.0	Changed document title from 'Electronic Listing Facility: Guidance on product changes' to 'Changing a listed or assessed listed medicine'. Application types and change tables and incorporated changes for assessed listed medicines.	Complementary and OTC Medicines Branch (COMB)	May 2020
V2.1	Minor addition of footnotes to definition of proprietary ingredient and Table D: Proprietary ingredient (PI) formulation changes.	COMB/SEB	July 2021
V2.2	Correction of error in number of application categories for listed medicines. Clarification of 9D(1) changes for L(A) applications. Minor clarification and addition of footnotes for A17 and A18. Addition of Table F and amendments to E01 and E02 to include pack size changes.	COMB	March 2022

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