Australian Government
Department of Health
Therapeutic Goods Administration

Changing a registered complementary medicine (RCM)

RCM application levels and changes tables

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TGA Health Safety Regulation

Contents

Application levels for RCM changes

Applications to change an Australian Register of Therapeutic Goods (ARTG) entry for a registered complementary medicine (RCM) are categorised into five levels (CN and RCM C1 to C4) based on increasing complexity– refer to Table A.

Applications in lower levels require less supporting information, have lower fees and reduced timeframes compared to applications in higher levels. It is important that you select the correct change codes from the RCM changes tables as these will determine the application level for you.

Table A: Change application levels for RCMs

Change level	Description
Notification request (CN)	Notification request changes are those changes where their implementation would not affect the established quality, safety or efficacy of the medicine. These have been determined by TGA to pose a very low risk. Notifications include changes to the quality and non-quality aspects of a medicine and do not require assessment of safety, efficacy and/or quality data (or a justification for not providing such data). After making an application to TGA requesting the variation and receiving an automated acknowledgment of acceptance of the submission, sponsors can implement the changes immediately. Refer to Notifications process: requests to vary registered medicines where quality, safety and efficacy are not affected for more information. Notification changes are identified in the Registered complementary medicines (RCM) changes tables as CN.
Application level 1 (RCM C1)	Application level 1 changes do not need safety, efficacy and/or quality data or a justification for not providing the data. Application level 1 changes are identified in the Registered complementary medicines (RCM) changes tables as RCM C1.
Application level 2 (RCM C2)	Application level 2 changes: • may require assessment of quality data • do not need safety and/or efficacy data or a justification for not providing the data Application level 2 changes are identified in the Registered complementary medicines (RCM) changes tables as RCM C2.

Change level	Description
Application level 3 (RCM C3)	Application level 3 changes: • include changes to the quality, safety and/or efficacy of a medicine • include changes to the medicine name where the new name requires a higher level of assessment, such as where there is an identified risk associated with an umbrella branding segment • require assessment of supporting safety and/or efficacy data or a justification for not providing the data Application level 3 changes are identified in the Registered complementary medicines (RCM) changes tables as RCM C3.
Application level 4 (RCM C4)	Application level 4 changes: • include changes to the safety and/or efficacy aspects of the medicine • require assessment of safety and/or efficacy data (clinical and/or toxicological) to support the proposed changes or a justification for not providing the data Application level 4 changes are identified in the Registered complementary medicines (RCM) changes tables as RCM C4.

Timeframes and fees for RCM change applications

All applications for changes to registered complementary 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 Therapeutic Goods Regulations 1990 (the Regulations) provide for legislated timeframes for applications to change registered complementary medicines. There are different timeframes for each of the Application levels for RCM changes. While the TGA is required to complete the assessment within the specified timeframes, applicants should not presuppose the outcome of an application. The timeframes for evaluation of changes for registered complementary medicines are provided in Table B.

Table B: Timeframes for the evaluation of registered complementary medicine changes

RCM change application category	Notification of acceptance of application (working days)	Timeframe (working days)
CN	-	N/A – automated approval

RCM change application category	Notification of acceptance of application (working days)	Timeframe (working days)
RCM C1	-	20
RCM C2	40	64
RCM C3	40	120
RCM C4	40	170

Within 40 working days of receiving an application for an RCM C2, C3 or C4 level application, the TGA delegate of the Secretary will notify the applicant in writing whether the application has passed preliminary assessment.

The legislated timeframe:

- only commences once an application is accepted for evaluation and any 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)

If the Secretary does not make a recommendation within the evaluation timeframe, the TGA must refund 25% of the prescribed fee.

Supportive documentation for RCM change applications

For most RCM change applications, you will need to submit supporting documentation. In some instances, certain assurances about the change will also need to be made before the application can proceed.

The Data requirements matrix for RCM changes provides the data requirements, based on the Common Technical Document (CTD) format, for the different types of Application levels for RCM changes.

In some circumstances, literature-based submissions may be appropriate. Refer to Literature-based submissions for listed medicines and registered complementary medicines.

How to use the code tables to determine RCM change type

The Registered complementary medicines (RCM) changes tables are a tool to help you obtain essential regulatory information about the proposed change for your Registered complementary medicine including:

- the relevant change codes required for your online application
- whether approval is needed to make the change (status codes)
- the type of assurances/data required to support the application
- the application level (CN and RCM C1 to RCM C4) for the change
- the section of the *Therapeutic Goods Act 1989* (the Act) that applies to the change request.

Identifying all planned changes in the RCM changes tables

Before you make a change to your complementary medicine, you will need to locate each planned change in the RCM changes tables so that you can:

- determine whether prior approval is required
- identify the change codes necessary to complete your application and determine the application level.

Ensure that you identify all changes that you intend to make, including changes that are consequential to the primary change. For example: If you are planning to delete an indication and, as a consequence, you need to change the directions for use, identify both the change to the indications and the change to the directions for use.

There are several alternative changes to indications and directions for use described in the RCM changes table, which have different conditions. You need to check which conditions apply in order to identify the correct change.

Check that you meet any conditions associated with the change, including those listed in the RCM changes table under column 4: 'Assurance codes'. Make sure you make the assurances corresponding to the assurance code when you submit your application in TGA Business Services.

If you cannot find your proposed change in the RCM changes table or you cannot meet the conditions for the change, go to RCM changes not in the RCM changes tables.

Determining whether prior approval is required

To determine if your proposed change requires prior TGA approval, check the status codes (column 3 in the RCM changes tables) associated with each change.

RCM changes requiring approval

You need TGA approval before changing the medicine if the status code for the proposed change is one of the following:

- SRR (safety-related request): Application made under subsection 9D(2) of the Act
- SAR (self-assessable request): Application made under subsection 9D(1) or 9D(3) of the Act
- A (approvable changes): Application made under subsection 9D(3) or section 23 of the Act

It is important that you identify all applicable change codes as you will need these to determine the application level and to complete your online application.

Each coded change that requires TGA approval corresponds to a particular application level based on risk. If a change requires TGA approval, you must wait to receive approval before making that change to your medicine.

RCM changes not requiring approval

If the status code for a change is 'O', you can make the change without submitting an application for TGA approval.

You cannot select changes with status code 'O' when you complete an application in TGA Business Services because you do not need TGA approval.

RCM changes that create a separate and distinct good

Some changes may result in a medicine being treated as a 'separate and distinct good' from the medicine currently included in the ARTG under section 16(1) of the Act.

The 'new' good must be separately entered in the ARTG. However, 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 R number to be retained for the new medicine. Applications to which the Groups Order applies are made under section 23B of the Act and all require prior TGA approval (most are status code A).

A grouping is appropriate when the goods are intended to replace the currently supplied goods, enabling the transition of one product to another. However, individual products within the group remain separate and distinct products under sections 16(1) and (1A) of the Act.

If a new registered complementary 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 register a new medicine and obtain a new AUST R number. For these applications, the status code is NEW (new application required)

RCM changes not in the RCM changes tables

If the change you plan to make for your RCM is not listed in the RCM changes tables, contact Complementary medicines because the absence of a code does not mean you can make the change to the ARTG record without notifying the TGA.

If we determine that the change you propose needs to be approved by us first and there is not an appropriate code in the changes tables, we will email you:

- endorsing the use of the 'other' change code
- advising you of the appropriate level for the application and the section of the Act that applies to the change

In your application, you need to:

- refer to our email in your application cover letter
- include our email in the dossier

Making more than one RCM change in one application

If you are making more than one change to your RCM, the application level is determined by the change that attracts the highest application level (CN is the lowest level and RCM C4 is the highest). For example: You lodge an application where you change three aspects of the ARTG entry: two RCM C1 level changes and one RCM C3 level change. Submit the application as an RCM C3 level application.

Registered Complementary Medicines (RCM) changes tables

The Act referred to in the following tables is the *Therapeutic Goods Act 1989.*

The RCM changes tables determine the following information about your change:

- the relevant change codes required for your online application (column 1)
- the proposed change (column 2)
- whether approval is needed (status codes) (column 3)
- the type of assurances/data required (column 4)
- the application level (column 5)
- the applicable section of the Act (column 6)

The RCM change tables consist of the following change types:

- Table 1: RCM labelling (including package insert) and product detail changes
- Table 2: RCM sponsor changes
- Table 3: RCM formulation changes - active ingredients
- Table 4: RCM formulation changes - excipient ingredients
- Table 5: RCM quality control changes - finished medicine specifications
- Table 6: RCM quality control changes - starting material specifications
- Table 7: RCM packaging changes
- Table 8: RCM manufacturing changes - finished product
- Table 9: RCM Consumer Medicine Information (CMI) changes
- Table 10: RCM Product Information (PI) changes Table
- Table 11: Other RCM changes

If the change you plan to make is not listed in the changes tables, refer to RCM changes not in the RCM changes tables.

For descriptions of the codes used in the RCM changes tables refer to:

- Table 12: RCM Status codes description –the types of application
- Table 13: RCM Assurance codes

RCM changes table 1: RCM labelling (including package insert) and product detail changes

Change codes	Labelling (including package insert) and product detail changes	Status codes	Assurance codes	Application level	Applicable section of the Act
GPN	Proprietary name (if grouping applies) where either: • the product name does **not** include an umbrella branded name; or • if it does contain an umbrella branded name, then the umbrella segment is not categorised as requiring a higher level of assessment	A	1, 2	RCM C2	23
GPU	Proprietary name (if grouping applies) where: • the product name includes an umbrella branded name **and** the umbrella segment is categorised as requiring a higher level of assessment; and/or • the product name has been amended to include a new 'fast acting' claim e.g. 'Farracet Rapid Tablets' on the basis of Module 5 data	A	1, 2	RCM C3	23
	Proprietary name (if grouping doesn't apply)	NEW			
GIN	New therapeutic indications (if grouping applies) where there is no requirement for supporting Module 4 and/or Module 5 data	A	1, 3	RCM C2	23
GID	New therapeutic indications (if grouping applies) where supporting Module 4 and/or Module 5 data or a justification for not providing the supporting data is required	A	1, 3	RCM C4	23
	New therapeutic indications (if grouping doesn't apply)	NEW			

Change codes	Labelling (including package insert) and product detail changes	Status codes	Assurance codes	Application level	Applicable section of the Act
LIW	Therapeutic indications or directions for use - change of wording without altering meaning	A	4, 5	RCM C2	9D(3)
LIS	Therapeutic indications - removal of sub-set of indications from label	SRR	5	RCM C1	9D(2)
LIR	Therapeutic indications - addition of registered indications to label	A	5	RCM C2	9D(3)
GDS	Directions for use – involves a reduction in the class of person for whom the goods are suitable e.g. changing a statement from *"not recommended for children under 12 years"* to *"not recommended for children or adolescents under 18 years"*	SRR	5	RCM C1	9D(2)
GDU	Directions for use - changes to the dosage instructions (if grouping applies), other than changes described in GDS or LIW, where there is no requirement for supporting Module 4 and/or Module 5 data	A	1, 3	RCM C2	23
GDD	Directions for use - changes to the dosage instructions (if grouping applies), where supporting Module 4 and/or Module 5 data or a justification for not providing the supporting data is required	A	1, 3	RCM C4	23
	Directions for use (if grouping doesn't apply)	NEW			
PSC	Recommended storage conditions - more restrictive	N	5	RCM CN	9D(2C)
PST	Recommended storage conditions - less restrictive	A	5	RCM C2	9D(3)

Change codes	Labelling (including package insert) and product detail changes	Status codes	Assurance codes	Application level	Applicable section of the Act
LSR	Addition of **more restrictive** safety-related statements including: • reduction in the class of person for whom the goods are suitable, e.g. changing a statement from "*not recommended for children under 12 years*" to "*not recommended for children or adolescents under 18 years*" • addition of a warning or precaution including a new RASML statement	SRR	5	RCM C1	9D(2)
LSF	Changes on label (signal headings, warning statements) in compliance with new SUSMP (Poisons Standard) requirements, where the change in scheduling is to a lower SUSMP schedule, except where LSC applies	A	5, 8	RCM C2	9D(3)
LSC	Changes on label (signal headings, warning statements) in compliance with new SUSMP (Poisons Standard) requirements, where the change in scheduling is to a lower SUSMP schedule where no such products have previously been approved as a complementary medicine	A	5, 8	RCM C3	9D(3)
LSU	Changes on label (signal headings, warning statements) in compliance with new SUSMP (Poisons Standard) requirements, other than LSF or LSC	SRR / SAR	5, 8	RCM C1	9D(2) / 9D(3)
LNT	Changes to bring a label into full compliance with the Therapeutic Goods Order No. 92 - other than changes to the proprietary name. If changing proprietary name (and where grouping applies), also use code GPN or GPU	A	5	RCM C2	9D(3)
LLR	Addition of a required representation to a label (Part 2 of Schedule 2 to the Therapeutic Goods Regulations 1990)	SRR	5, 7	RCM C1	9D(2)
LCF	Colour or type size change only (no change in label copy) other than where LFT applies	SAR	5	RCM C1	9D(3)

Change codes	Labelling (including package insert) and product detail changes	Status codes	Assurance codes	Application level	Applicable section of the Act
LFT	Font or type size other than change to the type size on the main panel of the label. Does not include change in colour or label copy.	N	5	CN	9D(2C)
LGR	Introduction of new graphics/icons (other than as specified in change LSP and KSP). For the addition of a TGA assessed claim to an existing, eligible RCM medicine, please see RCM changes table 11: Other RCM changes.	A	5	RCM C2	9D(3)
RGR	Removal of a graphic (other than as specified in change LAB for removal of sponsor logo or RGN).	SAR	5	RCM C1	9D(3)
RGN	Removal of a graphic except where this relates to directions on how to use the product or the use of a measuring device or an applicator (see KMD and KMO)	N	5	CN	9D(2C)
LFO	Reformatting of pre-existing text (i.e. moving or duplication of blocks of text and not rewording - see LIW, LDT, LDD) and/or movement of graphics (other than specified in LGM).	SAR	5	RCM C1	9D(3)
LGM	Movement of graphics provided it remains on the same panel of the label and there is no change to the size, shape or colour of the graphic and does not involve the reformatting of pre-existing text.	N	5	CN	9D(2C)
LLN	Introduction of a '*new*' or a '*value pack'* flash – see LAB for removal of a '*new*' or a '*value pack*' flash.	N	5	CN	9D(2C)
LSS	Introduction of text and/or graphics pertaining to sponsorship of a campaign or organisation, e.g. the Cancer Council's Pink Ribbon campaign or Surf Life Saving Australia.	A	5	RCM C1	9D(3)

Change codes	Labelling (including package insert) and product detail changes	Status codes	Assurance codes	Application level	Applicable section of the Act
LDT	Deletion or addition of text to the label (e.g. addition or removal of claims, such as clinically proven, fast/rapid action; general claims regarding the product, its nature, mechanism of action, qualifying statements, etc.)	A	5	RCM C2	9D(3)
LDD	Deletion or addition of text to the label where supporting Module 4 and/or Module 5 data or a justification for not providing the supporting data is required. For example, including a *'fast absorption'* claim on the label on the basis of new clinical data	A	5	RCM C3	9D(3)
KPI	Introduction of a package insert where there is no requirement for supporting Module 4 and/or Module 5 data. For example, including a CMI as a pack insert where the CMI is consistent with the product's approved product information	A	5, 29	RCM C2	9D(3)
KRI	Removal of a package insert (other than CMI)	A	5, 30	RCM C2	9D(3)
LSP	Changes to sponsor details including name and/or logo (inclusion of a logo or change to an existing logo) except where LAB applies	N	5	CN	9D(2C)
LAB	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 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 or Surf Life Saving Australia • deletion of sponsor logo provided the name and address of the sponsor or supplier of the goods are included on the label	O	-	-	-

Change codes	Labelling (including package insert) and product detail changes	Status codes	Assurance codes	Application level	Applicable section of the Act
	• inclusion, 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. See also KSL and KSX – trade mark (™) or registration (®) symbols or similar, or trademark statements e.g. Company XXY is a registered trademark of Company XXZ				

Change codes	Labelling (including package insert) and product detail changes	Status codes	Assurance codes	Application level	Applicable section of the Act
	• 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				
PSZ	Addition of a pack size for dosage forms other than liquids/semi-solids (see PLS) or metered dose aerosols (see PMZ) or as described in PSN	SAR	5, 6, 10	RCM C1	9D(3)
PSN	Addition of a pack size for dosage forms other than liquids/semi-solids (see PLS) or metered dose aerosols (see PMZ) where the new pack size falls within the approved pack size range. See also PSZ.	N	5, 6, 10	CN	9D(2C)
PLS	Addition of pack size for liquids/semi-solids other than as described in PLN	SAR	5, 6, 10, 13	RCM C1	9D(3)
PLN	Addition of pack size for liquids/semi solids where the new pack size falls within the approved pack size range. See also PLS.	N	5, 6, 10, 13	CN	9D(2C)
PMZ	Addition of pack size for metered dose aerosols	A	5,6	RCM C2	9D(3)
PSD	Pack size - deletion	N	5	CN	9D(2C)
	Dosage form (as defined in TGA approved terminology for medicines)	NEW			
PVI	Visual identification (note that novelty shapes, e.g. animal-shaped tablets, are not acceptable)	SAR	5, 13, 19, 27	RCM C1	9D(3)
PSL	Shelf life – increase	A	5	RCM C2	9D(3)

Change codes	Labelling (including package insert) and product detail changes	Status codes	Assurance codes	Application level	Applicable section of the Act
PSR	Shelf life - decrease	N	5	CN	9D(2C)
PMI	Sterility status	A	5	RCM C2	9D(3)

RCM changes table 2: RCM sponsor changes

RCM sponsor changes	Action required
Transfer of a good in the ARTG from one sponsor to another	Contact TGA Business Services help desk or see Notification of a change of sponsorship.
Changes to sponsor details on the labelling	See changes LAB and LSP; for changes to sponsor details in the Product Information (PI) see changes DAB and DAC

RCM changes table 3: RCM formulation changes - active ingredients

Change codes	Formulation changes - active ingredients	Status codes	Assurance codes	Application level	Applicable section of the Act
	Addition of active ingredient	NEW			
	Deletion of active ingredient	NEW			

Change codes	Formulation changes - active ingredients	Status codes	Assurance codes	Application level	Applicable section of the Act
	Amount of an active ingredient - see also Overages and batch to batch variation in CTD modules 2, 3, 4 and 5 for registered complementary medicine applications	NEW			
	Changes to herbal extracts outside the permitted variations as described within the Guidance on equivalence of herbal extracts in complementary medicines	NEW			
AOV	Overage - decrease or removal	N	5	CN	9D(2C)
AOA	Overage - increase	A	5	RCM C2	9D(3)
GPA	Replacement of a proprietary ingredient that contains an active substance with another proprietary ingredient where the only difference between the two proprietary ingredients (other than name) is to the amount of excipient ingredient(s) (if grouping applies)	A	1, 5	RCM C2	23
	Replacement of a proprietary ingredient that contains an active ingredient with another proprietary ingredient, other than as above in change GPA	NEW			

RCM Changes table 4: RCM formulation changes - excipient ingredients

Change codes	Formulation changes - excipient ingredients	Status codes	Assurance codes	Application level	Applicable section of the Act
ERT	Removal of a fragrance, flavour, printing ink and/or colouring agent(s) if the total agent(s) are present at not more than 2% w/w or w/v (if grouping applies) Note: this change may result in consequential changes to labelling (including the PI/CMI) and/or specifications (e.g. deletion from the label of declared ingredients or change to visual identification), which should also be addressed in accordance with the changes table.	SAR	1, 5, 13	RCM C1	23
GPI	Removal and/or addition of a fragrance, flavour, printing ink and/or colouring agent(s) (if grouping applies), other than change ERT	A	1, 5, 13	RCM C2	23
	Removal or addition of a fragrance, flavour, printing ink or colouring agent (if grouping doesn't apply)	NEW			
GPR	The replacement of one proprietary excipient ingredient with a different proprietary ingredient where the only difference between the two proprietary ingredients (other than name) is a change to the amount of an inactive component of the proprietary ingredient and/or manufacturing process (if grouping applies) other than ERT or GPI	A	1, 5, 13	RCM C2	23
	The replacement of one proprietary ingredient with a different proprietary ingredient other than in changes GPI or GPR	NEW			
	Addition or deletion of an excipient other than those above in change GPI	NEW			

Change codes	Formulation changes - excipient ingredients	Status codes	Assurance codes	Application level	Applicable section of the Act
GEX	Amount of excipient (if grouping applies) provided the content of the excipient is not higher than previously approved for the dosage form - See Overages and batch to batch variation in CTD modules 2, 3, 4 and 5 for registered complementary medicine applications	A	1, 5, 13	RCM C2	23
GED	Increase in the amount of an excipient (if grouping applies) where the content of the excipient is higher than previously approved for the dosage form - see 'Overages and batch to batch variation' in CTD modules 2, 3, 4 and 5 for registered complementary medicine applications	A	1, 5, 13	RCM C3	23
	Amount of excipient (if grouping doesn't apply) – see 'Overages and batch to batch variation' in CTD modules 2, 3, 4 and 5 for registered complementary medicine applications	NEW			
EST	Type of starch (no change to quantity)	N	5, 12	CN	9D(2C)

RCM Changes table 5: RCM quality control changes - finished medicine specifications

Change codes	Quality control changes - finished medicine specifications	Status codes	Assurance codes	Application level	Applicable section of the Act
QFX	Specification limits or requirements - more restrictive	O			
QFE	Specification limits or requirements - less restrictive (except where QFA applies); where any supporting data provided consist only of Module 3 (and not Module 4) data	A	5, 27	RCM C2	9D(3)

Change codes	Quality control changes - finished medicine specifications	Status codes	Assurance codes	Application level	Applicable section of the Act
QFF	Specification limits or requirements – less restrictive; where supporting Module 4 (nonclinical) data or a justification for not providing the supporting data is required. For example, a sponsor wishes to widen the limits for a related substance from the level normally applied of NMT 1% to NMT 3.5% and justifies the widening of the specification on the basis of a dossier which includes preclinical studies and published toxicology papers	A	5, 27	RCM C3	9D(3)
QFT	Addition of an extra test	O			
QFU	Deletion of an existing test where any supporting data provided consists only of Module 3 data	A	5, 27	RCM C2	9D(3)
QFD	Deletion of an existing test where supporting Module 4 data or a justification for not providing the supporting data is required. For example, a sponsor wishes to delete a particular test for a product that would normally be required but provides supporting data in the form of preclinical studies which support the sponsor's case for removal of the test from the specifications	A	5, 27	RCM C3	9D(3)
QFI	Frequency of testing – increase	O			
QFR	Frequency of testing - reduction	A	5, 27	RCM C2	9D(3)
QFA	Changes to the finished product specifications (test, test methods and limits/requirements) to comply with a standard as defined in the Act (e.g. the *British Pharmacopoeia* or a Therapeutic Goods Order), other than as specified in change MST. No non-pharmacopoeial test or requirements are concurrently deleted from the specification	O			
QFB	Analytical method (does not include changes to tests and limits and requirements), which has been demonstrated to maintain or improve analytical performance (accuracy, precision and/or specificity), other than as specified in change MST	O			

Change codes	Quality control changes - finished medicine specifications	Status codes	Assurance codes	Application level	Applicable section of the Act
QFC	Analytical method - other than as specified in change QFA, QFB or MST	A	5	RCM C2	9D(3)
QFP	Change from one default standard (as defined in the Act) to another (e.g. BP to USP) or from a '*company*' or '*in-house*' specification to a pharmacopoeial specification. This includes deletion of the existing pharmacopoeial tests and limits. This does not involve deletion of, or a change to, any current additional non-pharmacopoeial specifications, e.g. residual solvents in the finished product or friability.	N	5, 27	CN	9D(2C)

RCM Changes table 6: RCM quality control changes - starting material specifications

Change codes	Quality control changes—starting material specifications	Status codes	Assurance codes	Application level	Applicable section of the Act
QSX	Specification limits or requirements - more restrictive	O			
QSE	Specification limits or requirements - less restrictive (except where QSA applies); where any supporting data provided consist only of Module 3 (and not Module 4) data	A	5, 27	RCM C2	9D(3)
QSF	Specification limits or requirements – less restrictive; where supporting Module 4 data or a justification for not providing the supporting data is required. For example, a sponsor wishes to widen the limits for a related substance from the level normally applied of NMT 1% to NMT 3.5% and justifies the widening of the specification on the basis of a dossier which includes preclinical studies and published toxicology papers	A	5, 27	RCM C3	9D(3)

Change codes	Quality control changes—starting material specifications	Status codes	Assurance codes	Application level	Applicable section of the Act
QST	Addition of an extra test	O			
QSU	Deletion of an existing test where any supporting data provided consist only of Module 3 data	A	5, 27	RCM C2	9D(3)
QSD	Deletion of an existing test where supporting Module 4 data or a justification for not providing the supporting data is required. For example, a sponsor wishes to delete a particular test for a substance that would normally be required but provides supporting data in the form of preclinical studies that support the sponsor's case for removal of the test from the specifications	A	5, 27	RCM C3	9D(3)
QSA	Changes to the starting material specifications (test, test methods and limits/requirements) to comply with a standard as defined in the Act (e.g. the BP or a Therapeutic Goods Order). No non-pharmacopoeial test or requirements are concurrently deleted from the specification, e.g. a specification for particle size distribution	O			
QSB	Analytical method (does not include changes to test limits and requirements), which has been demonstrated to maintain or improve analytical performance (accuracy, precision and/or specificity)	O			
QSC	Analytical method - other than as specified in change QSA or QSB	A	5	RCM C2	9D(3)
QSM	Manufacturer of starting material (specifications unchanged)	O			
QSS	Supplier of starting material	O			

Change codes	Quality control changes—starting material specifications	Status codes	Assurance codes	Application level	Applicable section of the Act
QSP	Change from one '*default standard*' (as defined in the Act) to another (e.g. BP to USP) or from a '*company*' or '*in-house*' specification to a pharmacopoeial specification. This includes deletion of the existing pharmacopoeial tests and limits. This does not include deletion of, or a change to, any current additional non-pharmacopoeial specifications, e.g. particle size distribution.	N	5	CN	9D(2C)

RCM Changes table 7: RCM packaging changes

Change codes	Packaging changes	Status codes	Assurance codes	Application level	Applicable section of the Act
	Container type (as defined in TGA approved terminology for medicines)	NEW			
KBT	Container material - if the container is a bottle, the goods are a solid dosage form (e.g. tablet) and the change in material is of a type described below: • polystyrene to PVC, polyethylene, polypropylene or glass • PVC to polyethylene, polypropylene or glass • polyethylene to glass or polypropylene of density ≥ 0.89 • from one density of polyethylene to a higher density • any change between glass, polyethylene of density ≥ 0.95, and polypropylene of density ≥ 0.89	N	5, 13, 16 & 25	CN	9D(2C)
KGL	Container material - clear to coloured glass	O			

Change codes	Packaging changes	Status codes	Assurance codes	Application level	Applicable section of the Act
KBL	Container material - if the container is a blister pack, the goods are a solid dosage form (e.g. tablet) and the change in material is of a type described below: • PVC to PVC/PVDC or to PVC/PCTFE • PVC/PVDC to PVC/PCTFE or the change to the plastic component is to a material with demonstrated lower or equivalent water permeability than the existing material (see for example USP monograph '*<671> Containers Permeation*')	N	5, 13 & 25	CN	9D(2C)
KCI	Container – increase in container wall thickness	O			
KCD	Container – decrease in container wall thickness, except where KBT, KBL	A	5	RCM C2	9D(3)
KOT	Container material – other than in changes KBT, KGL, KBL, KCI, KCD	A	5	RCM C2	9D(3)
KCL	Closure – other than changes in KCM or MDA	N	5, 13	CN	9D(2C)
KCM	Closure, where the closure also serves as a metering component (other than MDA)	A	5	C2	9D(3)
MDA	Changes in pump or pump components of meter-dose aerosol (e.g. valve material)	A	5	C2	9D(3)
KSL	Tamper evident seal - addition (including label notice to alert consumers to presence of seal). See also LAB	O			
KSX	Tamper evident seal - removal (including removal of label notice re seal). See also LAB	O			
KWA	Inert wadding material - addition, substitution or removal where stability is not affected by the action	O			
KDA	Desiccant - inclusion in container	A	5	RCM C2	9D(3)

Change codes	Packaging changes	Status codes	Assurance codes	Application level	Applicable section of the Act
KDX	Desiccant - removal from container	A	5	RCM C2	9D(3)
KPP	Specifications of primary pack except where the primary pack is also the container Does not include any other changes to the labelling such as text, graphics, colour, font, etc. Note: primary pack is defined in subsection 3(1) of the Act as *'primary pack, in relation to therapeutic goods, means the complete pack in which the goods, or the goods and their container, are to be supplied to consumers'*	O			
KSP	Introduction of a measuring device (e.g. spoon, cylinder) or applicator (e.g. finger cot). This change can include graphical representation (and associated wording where required) of the device on the label. A copy of current and proposed label must be supplied if the label is changed	SAR	5, 24	RCM C1	9D(3)
KMO	Removal of a measuring device where other means of accurately measuring the dose are readily available. This change can include the deletion of graphical representation of the device (including associated wording) on the label Does not include changes to the directions for use or any other changes to labelling, such as reformatting. A copy of current and proposed label must be supplied if the label is changed.	N	5	CN	9D(2C)
KMD	Changes to existing measuring device (e.g. spoon, cylinder) or applicator supplied with the goods or removal of an applicator, where other means of accurately administering the dose are readily available. This change can include changes to the graphical representation (and associated wording where required) of the device on the label. It can also include the addition or deletion of graphical representation (including associated wording) of the device on the label. A copy of current and proposed label must be supplied if the label is changed.	SAR	5, 24	RCM C1	9D(3)

Change codes	Packaging changes	Status codes	Assurance codes	Application level	Applicable section of the Act
KPA	Introduction of a primary pack (no new text or graphics) Note: primary pack is defined in subsection 3(1) of the Act as *'primary pack, in relation to therapeutic goods, means the complete pack in which the goods, or the goods and their container, are to be supplied to consumers'*	SAR	5, 14	RCM C1	9D(3)
KPX	Removal of a primary pack	SAR	5, 17	RCM C1	9D(3)
KRP	Introduction of a refill pack	A	5	RCM C2	9D(3)
KRR	Removal of refill pack	N	5	CN	9D(2C)

RCM Changes table 8: RCM manufacturing changes - finished product

Change codes	Manufacturing changes - finished product	Status codes	Assurance codes	Application level	Applicable section of the Act
MMA	Addition of a manufacturer (includes site of manufacture), other than for sterile products where MSS or MST applies	N	5, 9	CN	9D(2C)
MMD	Deletion of a manufacturer (includes site of manufacture)	N	5	CN	9D(2C)
AMS	Addition of steps of manufacture, other than for sterile products where MSS or MST applies	N	5, 9	CN	9D(2C)
MSD	Deletion of steps of manufacture	N	5	CN	9D(2C)
MPT	Manufacturing process: tightening of in-process limits and/or introduction of an additional in-process control	O			

Change codes	Manufacturing changes - finished product	Status codes	Assurance codes	Application level	Applicable section of the Act
MPR	Manufacturing process other than for 'higher risk' complementary medicines (see MPH or MPD) or for sterile products (see MSS or MST). See also MPT	SAR	5, 13	RCM C1	9D(3)
MPH	Manufacturing process for the following 'higher risk' complementary medicines: • microdose products (solid oral dosage forms where the active ingredient is present in an amount of less than 2 mg or 2% w/w of the dosage form) • products with a sustained-release characteristic (not including enteric-coated products) • metered dose inhalers • where the changes to the product have been demonstrated to be equivalent to or superior to the approved manufacturing process	SAR	5, 13	RCM C1	9D(3)
MPD	Manufacturing process for the following 'higher risk' complementary medicines: • microdose products (solid oral dosage forms where the active ingredient is present in an amount of less than 2 mg or 2% w/w of the dosage form) • products with a sustained release characteristic (not including enteric-coated products) • metered dose inhalers • except where MPH applies	A	5, 13	RCM C2	9D(3)
MUP	GMP clearance number update only; no other change to the product	SAR (fee exempt)	5	RCM C1	9D(3)

Change codes	Manufacturing changes - finished product	Status codes	Assurance codes	Application level	Applicable section of the Act
MSS	For a sterile product (other than where MST applies): • Addition of a manufacturer (includes site of manufacture) involving **only** one or more of the following steps: release for supply, secondary packaging or testing (chemical and physical or microbial) • Addition of steps of manufacture involving **only** one or more of the following steps: release for supply, secondary packaging or testing (chemical and physical or microbial)	N	5, 9	CN	9D(2C)
MST	For a sterile product: • Addition of a manufacturer (includes site of manufacture) other than where MSS applies • Addition of steps of manufacture other than where MSS applies • Change in the manufacturing process	A	5	RCM C2	9D(3)

RCM Changes table 9: RCM Consumer Medicine Information (CMI) changes

Change codes	Consumer Medicine Information (CMI)	Status codes	Assurance codes	Application level	Applicable section of the Act
CPI	Introduction of a CMI for a 'Pharmacist Only Medicine' (Schedule 3) product registered after 4 July 1995 where the CMI complies with Schedule 13 to the Therapeutic Goods Regulations 1990 and is not to be included as a package insert. Note: Change KPI applies where the CMI is to be included as a package insert.	O			

Change codes	Consumer Medicine Information (CMI)	Status codes	Assurance codes	Application level	Applicable section of the Act
CPO	Changes to an existing CMI, where the changes are consistent with all previously approved product details and the CMI is not to be included as a package insert. Note: Refer to Labelling (including package insert) and medicine detail changes on changes to a CMI where the CMI is to be included as a package insert (package inserts are treated as part of the label).	O			

RCM Changes table 10: RCM Product Information (PI) changes

Change codes	Product Information (PI)	Status codes	Assurance codes	Application level	Applicable section of the Act
DPI	Introduction of Product Information (PI) for an existing product where there is no requirement for supporting Module 4 and/or Module 5 data. For example, where the PI is essentially the same as the PI of the originator medicine	A	5	RCM C2	9D(3)
DPD	Introduction of Product Information (PI) for an existing product where supporting Module 4 and/or Module 5 data or a justification for not providing the supporting data is required. For example, where the PI includes information on clinical trials and Module 5 data are provided to substantiate the information included in the PI	A	5	RCM C3	9D(3)
DAB	Minor editorial changes 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 rewording or the deletion of sentences or phrases • deletion of sponsor logo provided the name and address of the sponsor is included in the PI • inclusion, removal or changes to: – country of origin statement (e.g. '*Made in XX*')	O			

Change codes	Product Information (PI)	Status codes	Assurance codes	Application level	Applicable section of the Act
	– 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 of the goods is included in the PI – supplier/manufacturer name, address and/or contact details – Australian Business name/Australian Company name – product code number (or equivalent) or an overseas registration number – trade mark (™) or registration (®)symbols or similar or trademark statements e.g. Company XXY is a registered trademark of Company XXZ				
DAC	Updating the PI to reflect the currently approved product details or changes consequential to other changes made in the same application. Changes are limited to the following: • storage conditions • sponsor details including sponsor name and/or logo (inclusion of a logo or change of an existing logo) except where DAB applies • container or pack size details • visual identification • dosage form • route of administration • formulation details • poisons schedule • proprietary name • indications (where the wording is identical to that included in the ARTG or that proposed for the ARTG as part of the same application) Does not include changes to the directions for use	SAR	5	RCM C1	9D(3)

Change codes	Product Information (PI)	Status codes	Assurance codes	Application level	Applicable section of the Act
DRS	Addition of **more restrictive** safety-related statements including: • reduction in the class of person for whom the goods are suitable, e.g. changing a statement from "*not recommended for children under 12 years*" to "*not recommended for children or adolescents under 18 years*" • addition of a warning or precaution including a new RASML statement or new statement required in permitted ingredient determination. (See also LSR for consequential changes to labelling)	SRR	5	RCM C1	9D(2)
DOT	Changes (including addition or deletion of text or the rewording or reformatting of existing text) where there is no requirement for supporting Module 4 and/or Module 5 data, other than as specified in change DAB, DAC or DRS	A	5	RCM C2	9D(3)
DOD	Changes other than the addition of more restrictive safety-related statements where supporting Module 4 and/or Module 5 data or a justification for not providing the supporting data is required. For example, updating the section on Clinical Trials where the changes made are supported by Module 5 data	A	5	RCM C3	9D(3)
DRP	Removal of a PI where the PI is not required under section 25AA of the Act.	A	5	RCM C2	9D(3)

RCM Changes table 11: Other RCM changes

Change codes	Other	Status codes	Assurance codes	Application level	Applicable section of the Act
CTA	Correction of ARTG record in accordance with section 9D(1) of the Act. Evidence to support the change is included with the application	SAR	5, 21	RCM C1	9D(1)

Change codes	Other	Status codes	Assurance codes	Application level	Applicable section of the Act
CAO	Correction of ARTG record in accordance with section 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	SAR (fee exempt)	5, 21, 31	RCM C1	9D(1)
OT1	'Other' changes – application level C1. An 'other' code is used only when no other code applies. An application using OT1 must include written advice from the TGA advising the use of this change code for the requested change to the product. Please note that applications for eligible RCMs who wish to add a TGA assessed label claim to their medicine may use this change code	ASK	31	RCM C1	Specified in advice from TGA
OT2	'Other' changes – application level C2. An 'other' code is used only when no other code applies. An application using OT2 must include written advice from the TGA advising the use of this change code for the requested change to the product	ASK	31	RCM C2	Specified in advice from TGA
OT3	'Other' changes – application level C3. An 'other' code is used only when no other code applies. An application using OT3 must include written advice from the TGA advising the use of this change code for the requested change to the product	ASK	31	RCM C3	Specified in advice from TGA
OT4	'Other' changes – application level C4. An 'other' code is used only when no other code applies. An application using OT4 must include written advice from the TGA advising the use of this change code for the requested change to the product	ASK	31	RCM C4	Specified in advice from TGA
OTX	'Other changes – application level CN. This code is to be used to request CN level changes to multiple ARTG entries. This code must be used in addition to other change types that result in a CN level application. The details of the additional products, including relevant ARTG IDs must be provided. Additional processing time will be required.	N	As required for the	CN	9D(2C)

RCM changes table 12: RCM status codes-the type of application

Code	Prior TGA approval required?	Description
A	Yes	A change made under section 9D or section 23 of the Act
SRR	Yes	Safety Related Request: a change made under section 9D(2) of the Act
SAR	Yes	Self-Assessable Request: a change made under section 9D(1) or section 9D(3) of the Act
N	Yes	Notifications: a change made under section 9D(2C) of the Act. TGA approval is made automatically upon lodgement and payment of the application.
NEW	Yes	New application for registration required
O	No	The TGA does not need to be informed of changes subject to status code 'O' – no application is submitted. Note 1: Change codes for 'O' status changes are not included in the application portal. Note 2: Changes with status 'O' have been included in the changes table for clarity and completeness and do not imply that this information is required for evaluation of an equivalent new product.
ASK	Yes	This applies only where one of the 'other' change codes (OT1, OT2, OT3 or OT4) is used. Refer to RCM changes not in the RCM changes table.

RCM changes table 13: RCM assurance codes

Code	Description
1.	The 'new' goods are intended to replace the existing goods in use
2.	The only difference between the 'new' goods and the existing goods is the name
3.	The only differences between the 'new' goods and the existing goods are related to the indications for use and/or the directions for use
4.	No additional indications have been introduced or directions for use altered (other than change to wording)

Code	Description
5.	No aspects of the labelling, PI, CMI, pharmaceutical data or other product details (including manufacturing process) have been changed or are to be changed, other than changes nominated in this application and those made in conformity with the changes table
6.	The labelling for the new pack size is unchanged, other than to indicate the new pack size number/volume
7.	The only changes made are those that bring the label into compliance with requirements of the Labelling Order, or Schedule 2 to the Therapeutic Goods Regulations 1990
8.	The change is in compliance with a requirement introduced in the most recent version or amendment of the SUSMP (Poisons Standard).
9.	The nominated manufacturer is licensed to manufacture goods of this type
10.	The container type (as defined in TGA approved terminology for medicines) is unchanged and container material is unchanged
11.	A stability testing protocol has been approved for this product and a copy of the approval letter is attached
12.	All of the following apply: Neither the existing nor the new material is a modified starch. The changeover has been validated. At least 6 month's stability data have been generated at the maximum recommended storage temperature on product manufactured using the new type of starch, or 3 month's data at a temperature at least 10°C higher than the maximum recommended storage temperature. Stability testing will continue for the full term of the product's shelf life and any batches not meeting specifications will be withdrawn from the market immediately and the TGA notified immediately.
13.	All of the following apply: The changeover has been validated* and the Sponsor is satisfied that the change will not adversely affect the stability of the product. Stability testing will continue for the full term of the product's shelf life and the TGA advised immediately of any batches not meeting specifications. *Note: Validation data will be provided during a GMP inspection or upon request by the TGA within 3 months following the request
14.	No new text or graphics have been introduced

Code	Description
15.	Intentionally blank
16.	The new container/closure system has demonstrated equal or better moisture protection in the USP test for Containers – Permeation (water vapour transmission) to that of the existing container/closure system
17.	The information on the container label is not less than the information on the primary pack
18.	Intentionally blank
19.	Manufacturing method and specifications, other than visual identification, have not been changed
20.	Two production batches have been tested according to the approved stability protocol and all results fall within the acceptance criteria, as specified in the approved stability protocol
21.	The changes are in accordance with s.9D(1) of the Act
22.	Intentionally blank
23.	Intentionally blank
24.	Where a measuring device is being introduced or changed, it includes calibrations exclusively in metric units and will allow all the doses shown on the label to be measured accurately
25.	The container type (as defined in TGA approved terminology for medicines) is unchanged
26.	Intentionally blank
27.	A copy of the current specification plus a copy of the new specification, with the changes highlighted, have been supplied
28.	Intentionally blank
29.	A copy of the current label of the goods together with a draft copy of the new package insert have been supplied
30.	A copy of the current label and package insert of the goods have been supplied
31.	A copy of the written advice from TGA advising the use of this change code for the requested change to the product has been supplied

Information required for an RCM change application

The information required to support a change to an existing ARTG entry registered complementary medicine depends on the application type - use the Registered complementary medicines (RCM) changes tables to determine your application level.

Data requirements matrix for RCM changes

How to use the matrix

Use the matrix (data matrix tables 1 to 4) to obtain an indication of which documents you need to provide for your application level. The information included in CTD modules 2, 3, 4 and 5 for registered complementary medicine applications provide assistance in determining what documents are required.

For full folder names, refer to ICH guidance: Common technical document (CTD).

The codes in the matrix are provided in Data matrix table 6.

Data matrix table 1: CTD Module 1 data requirements for RCM changes

Module	Name	C1	C2	C3	C4	File or folder name
1.0	**Correspondence**	R	R	R	R	100-correspondence
1.0.1	Cover letter	R	R	R	R	1001-cover
1.1	**Comprehensive table of contents**	R	R	R	R	101-toc
1.2	**Administrative information**	D	D	D	D	102-admin-info
1.2.3	Patent certification	D	D	D	D	1023-pat-cert
1.3	**Medicine information and labelling**	D	D	D	D	103-med-info
1.3.1	Product Information and package insert	D	D	D	D	1031-pi
1.3.1.1	Product information – clean	D	D	D	D	10311-pi-clean

Module	Name	C1	C2	C3	C4	File or folder name
1.3.1.2	Product information – annotated	D	D	D	D	10312-pi-annotated
1.3.1.4	Package insert	D	D	D	D	10314-pack-ins
1.3.2	Consumer medicines information (CMI)	D	D	D	D	1032-cmi
1.3.2.1	CMI – clean	D	D	D	D	10321-cmi-clean
1.3.2.2	CMI – annotated	D	D	D	D	10322-cmi-annotated
1.3.3	Label mock-ups and specimens	D	D	D	D	1033-mock-ups
1.4	**Information about the experts**			D	D	104 experts
1.4.1	Quality			D	D	1041-quality
1.4.2	Nonclinical			D	D	1042-nonclinical
1.4.3	Clinical			D	D	1043-clinical
1.5	**Specific requirements for different types of applications**	D	D	D	D	105-specific
1.5.1	Literature-based submission documents			D	D	1051-lit-based
1.5.5	Co-marketed medicines declarations					1055-co-marketed
1.5.7	OTC New product assurances					1057-assurance
1.5.8	Umbrella brand assessment			D	D	1058-umbrella-br-assess
1.7	**Compliance with meetings and pre-submission processes**	D	D	D	D	107-compliance
1.7.1	Details of compliance with pre-submission meeting outcomes					1071-pre-sub-outcomes
1.7.2	Details of any additional data to be submitted					1072-additional-data

Module	Name	C1	C2	C3	C4	File or folder name
1.8	**Information relating to pharmacovigilance**			D	D	108-pharmacovigilance
1.9	**Summary of biopharmaceutic studies**		D	D	D	109-biopharm
1.9.1	Summary of bioavailability or bioequivalence study			D	D	1091-ba-be
1.11	**Foreign regulatory information**	D	D	D	D	111-foreign
1.11.1	Foreign regulatory status	D	D	D	D	1111-status
1.11.2	Foreign product information	D	D	D	D	1112-pi
1.11.3	Data similarities and differences	D	D	D	D	1113-similarities
1.11.4	Foreign evaluation reports	D	D	D	D	1114-eval-reports

Data matrix table 2: CTD Module 2 data requirements matrix for RCM changes

Module	Name	C1	C2	C3	C4	File or folder name
2	**CTD Summaries**					m2
2.2	**CTD introduction**			O	O	22-intro
2.3	**Quality overall summary**					23-qos
2.4	**Nonclinical overview**			O	O	24-nonclin-over
2.5	**Clinical overview**			D	D	25-clin-over
2.6	**Nonclinical written and tabulated summaries**			D	D	26-nonclin-sum
2.7	**Clinical summary**			D	D	27-clin-sum

Data matrix table 3: CTD Module 3 data requirements for RCM changes

Module	Name	C1	C2	C3	C4	File or folder name
3	**Quality**		D	D		m3
3.2.S	**Drug substance**					32s-drug-sub

Module	Name	C1	C2	C3	C4	File or folder name
3.2.S.1	**General Information**					32s1-gen-info
3.2.S.1.1	Nomenclature					nomenclature
3.2.S.1.2	Structure					structure
3.2.S.1.3	General Properties		D	D		general-properties
3.2.S.2	**Manufacture**					32s2.2-manuf
3.2.S.2.1	Manufacturer		D	D		manufacturer
3.2.S.2.2	Description of manufacturing process and process controls		D	D		manuf-process-and-controls
3.2.S.2.3	Control of materials		D	D		control-of-materials
3.2.S.3	**Characterisation**		D	D		32s3-charac
3.2.S.3.1	Elucidation of structure and other characteristics		D	D		elucidation-of-structure
3.2.S.3.2	Impurities		D	D		impurities
3.2.S.4	**Control of Drug Substance**	O	D	D		32s4-contr-drug-sub
3.2.S.4.1	Specification	O	D	D		32s41-spec
3.2.S.4.2	Analytical Procedures	O	D	D		32s42-analyt-proc
3.2.S.4.3	Validation of analytical procedures	O	D	D		32s43-val-analyt-proc
3.2.S.4.4	Batch analyses	O	D	D		32s44-batch-analys
3.2.S.4.5	Justification of Specification	O	D	D		32s45-justif-spec
3.2.S.5	**Reference standards or materials**		D	D		32s5-ref-stand
3.2.S.6	**Container closure system**		O	O		32s6-cont-closure-sys
3.2.S.7	**Stability**		D	D		32s7-stab
3.2.S.7.1	Stability summary and conclusions		D	D		stability-summary
3.2.S.7.3	Stability data		D	D		stability-data

Module	Name	C1	C2	C3	C4	File or folder name
3.2.P	**Drug product**					32p-drug-prod
3.2.P.1	**Description and composition of the drug product**		D	D		32p1-desc-comp
3.2.P.2	**Pharmaceutical development**		D	D		32p2-pharm-dev
3.2.P.2.1	Components of the drug product		D	D		
3.2.P.2.1.1	Drug Substance		O	O		
3.2.P.2.1.2	Choice of the excipients listed in 3.2.P.1		O	O		
3.2.P.2.2	Drug Product		D	D		
3.2.P.2.2.1	Formulation development		D	D		
3.2.P.2.2.2	Overages	D	D	D		
3.2.P.2.2.3	Physicochemical and biological properties		D	D		
3.2.P.2.3	Manufacturing process development		D	D		
3.2.P.2.4	Container Closure System	D	D	D		
3.2.P.2.5	Microbiological attributes		D	D		
3.2.P.2.6	Compatibility		D	D		
3.2.P.3	**Manufacture**					32p3-manuf
3.2.P.3.1	Manufacturer(s)	D	D	D		manufacturers
3.2.P.3.2	Batch formula		D	D		batch-formula
3.2.P.3.3	Description of manufacturing process and process controls	D	D	D		manuf-process-and-controls
3.2.P.3.4	Controls of critical steps and intermediates		D	D		control-critical-steps
3.2.P.3.5	Process validation and/or evaluation		D	D		process-validation
3.2.P.4	**Control of excipients**					32p4-contr-excip

Module	Name	C1	C2	C3	C4	File or folder name
3.2.P.4.1	Specifications	O	D	D		specifications
3.2.P.4.2	Analytical procedures	O	D	D		analytical-procedures
3.2.P.4.3	Validation of analytical procedures	O	D	D		validation-analyt-procedures
3.2.P.4.4	Justification of specifications	O	D	D		justification-of-specifications
3.2.P.4.5	Excipients of human or animal origin		D	D		excipients-human-animal
3.2.P.4.6	Novel excipients		D	D		novel-excipients
3.2.P.5	**Control of drug product**					32p5-contr-drug-prod
3.2.P.5.1	Specification(s)	O	D	D		32p51-spec
3.2.P.5.2	Analytical procedures	O	D	D		32p52-analyt-proc
3.2.P.5.3	Validation of analytical procedures	O	D	D		32p53-val-analyt-proc
3.2.P.5.4	Batch analyses		D	D		32p54-batch-analys
3.2.P.5.5	Characterisation of impurities		D	D		32p55-charac-imp
3.2.P.5.6	Justification of specifications	O	D	D		32p56-justif-spec
3.2.P.6	**Reference standards or materials**		D	D		32p6-ref-stand
3.2.P.7	**Container closure system**		D	D		32p7-cont-closure-sys
3.2.P.8	**Stability**		D	D		32p8-stab
3.2.P.8.1	Stability summary and conclusion		D	D		stability-summary
3.2.P.8.3	Stability data		D	D		stability-data

Data matrix table 4: CTD Module 4 data requirements for RCM changes

Module	Name	C1	C2	C3	C4	File or folder name
4	**Nonclinical study reports**			D	D	m4
4.1	**Table of contents**			D	D	41-toc

Module	Name	C1	C2	C3	C4	File or folder name
4.2	**Study reports**			D	D	42-stud-rep
4.2.1	**Pharmacology**			D	D	421-pharmacol
4.2.1.1	Primary pharmacodynamics			D	D	4211-prim-pd
4.2.1.2	Secondary pharmacodynamics			D	D	4212-sec-pd
4.2.1.3	Safety pharmacology			D	D	4213-safety-pharmacol
4.2.1.4	Pharmacodynamic drug interactions			D	D	4214-pd-drug-interact
4.2.2	**Pharmacokinetics**			D	D	422-pk
4.2.2.1	Analytical methods and validation reports			D	D	4221-analyt-met-val
4.2.2.2	Absorption			D	D	4222-absorp
4.2.2.3	Distribution			D	D	4223-distrib
4.2.2.4	Metabolism			D	D	4224-metab
4.2.2.5	Excretion			D	D	4225-excr
4.2.2.6	Pharmacokinetic drug interactions			D	D	4226-pk-drug-interact
4.2.2.7	Other pharmacokinetic studies			D	D	4227-other-pk-stud
4.2.3	**Toxicology**			D	D	423-tox
4.2.3.1	Single-dose toxicity			D	D	4231-acute-tox
4.2.3.2	Repeat-dose toxicity			D	D	4232-repeat-dose-tox
4.2.3.3	**Genotoxicity**			D	D	4233-genotox
4.2.3.3.1	In vitro			D	D	42331-in-vitro
4.2.3.3.2	In vivo			D	D	42332-in-vivo
4.2.3.4	**Carcinogenicity**			D	D	4.2.3.4
4.2.3.4.1	Long-term studies			D	D	42341-lt-stud
4.2.3.4.2	Short- or medium-term studies			D	D	42342-smt-stud
4.2.3.5	**Reproductive and developmental toxicity**			D	D	4235-repro-dev-tox
4.2.3.5.1	Fertility and early embryonic development			D	D	42351-fert-embryo-dev
4.2.3.5.2	Embryo-fetal development			D	D	42352-embryo-fetal-dev

Module	Name	C1	C2	C3	C4	File or folder name
4.2.3.5.3	Prenatal and postnatal development, including maternal function			D	D	42353-pre-postnatal-dev
4.2.3.5.4	Studies in which the offspring (juvenile animals) are dosed and/or further evaluated			D	D	42354-juv
4.2.3.6	**Local tolerance**			D	D	4236-loc-tol
4.2.3.7	**Other toxicity studies**			D	D	4237-other-tox-stud
4.2.3.7.1	Antigenicity			D	D	42371-antigen
4.2.3.7.2	Immunotoxicity			D	D	42372-immunotox
4.2.3.7.3	Mechanistic studies			D	D	42373-mechan-stud
4.2.3.7.4	Dependence			D	D	42374-dep
4.2.3.7.5	Metabolites			D	D	42375-metab
4.2.3.7.6	Impurities			D	D	42376-imp
4.3	**Literature references**			D	D	43-lit-ref

Data matrix table 5: CTD Module 5 data requirements for RCM changes

Module	Name	C1	C2	C3	C4	File or folder name
5	**Clinical study reports**					m5
5.1	**Table of contents**			D	D	51-toc
5.2	**Tabular listing of all clinical studies**			D	D	52-tab-list
5.3	**Clinical study reports**			D	D	53-clin-stud-rep
5.3.1	Reports of biopharmaceutic studies			D	D	531-rep-biopharm-stud
5.3.2	Reports of studies pertinent to pharmacokinetics using human biomaterials			D	D	532-rep-stud-pk-human-biomat
5.3.3	Reports of human pharmacokinetic (PK) studies			D	D	533-rep-human-pk-stud
5.3.4	Reports of human pharmacodynamic (PD) studies			D	D	534-rep-human-pd-stud
5.3.5	**Reports of efficacy and safety studies**			D	D	535-rep-effic-safety-stud

Module	Name	C1	C2	C3	C4	File or folder name
5.3.5.1	Study reports of controlled clinical studies pertinent to the claimed indication			D	D	5351-stud-rep-contr
5.3.5.2	Study reports of uncontrolled clinical studies			D	D	5352-stud-rep-uncontr
5.3.5.3	Reports of analyses of data from more than one study			D	D	5353-rep-analys-data-more-one-stud
5.3.5.4	Other study reports			D	D	5354-other-stud-rep
5.3.6	Reports of post-marketing experience			D	D	536-postmark-exp
5.4	**Literature references**			D	D	54-lit-ref

Data matrix table 6: Description of codes used in data matrix

Code	Description
R (red)	The document(s) and/or appropriate scientific justification for not providing document(s) are required for a valid application.
D (green)	The document(s) are dependent on the kind of application in a particular category for the particular dossier. For example 'D' is listed for Product information in Module 1.
O (blue)	The document(s) are optional. There is no requirement for the document(s) to be submitted with the application. However, the document(s) can be provided if the applicant considers the information is relevant to the application.
Blank	The document(s) are not relevant and should not be submitted

Version history

Version	Description of change	Author	Effective date
V1.0	Information for original publication extracted from ARGCM V9 (pages 207-238). Changes include: • restructuring information on change application levels into a table • renaming change application levels from C1 - C4 to RCM C1 - RCM C4 to be consistent with legislation and clearly identify that these changes are for RCMs • including information on timeframes and fees for RCM change applications • including information on supportive documentation for RCM change applications • including information on how to use the code tables • inclusion of a list of the changes tables • numbering of the change tables • addition of information on applying to use the TGA assessed claim • inclusion of the data matrix for data requirements for RCM changes • changing headings and numbers in change tables to be consistent with docu-bridge	Complementary & OTC Medicines Branch	May 2020

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

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