Australian Government
Department of Health
Therapeutic Goods Administration

Changing an OTC medicine: using the Changes Tables

Version 2.4, 4 December 2017

TGA Health Safety Regulation

Contents

Introduction

This guidance is for sponsors planning to change a registered over-the-counter (OTC) medicine. It:

- contains the OTC Changes table, which is a tool to help you obtain essential regulatory information about your 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 relevant change codes; these are required to complete your application
  - the application level for the change.
- explains how to use the OTC Changes table.

Related information and guidance

- Process to change a registered OTC medicine <https://www.tga.gov.au/publication/process-change-registered-otc-medicine>
- Australian regulatory guidelines for OTC medicines <https://www.tga.gov.au/publication/australian-regulatory-guidelines-otc-medicines-argom-0>

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 Changes table 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.

- Check that you meet any conditions associated with the change, including those listed in the Changes Table under 'Assurance codes'.
  - You are required to make the relevant assurances corresponding to the assurance code when you submit your application in eBusiness Services <https://www.ebs.tga.gov.au/>.
- If you cannot find your proposed change in the Changes table or you cannot meet the conditions for the change, go to Changes not included in the Changes Table.

Example

If you are planning to delete an indication and a consequential change is also required to the directions for use, you must 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 Changes Table, which have different conditions. You need to check which conditions apply in order to identify the correct change.

Determining whether prior approval is required

To determine if your proposed change requires prior TGA approval, check the status codes associated with each change in the Changes Table.

- If the status code for a change is 'O', you can make the change without submitting an application for TGA approval.
  - Changes with status code 'O' cannot be selected when you complete an application in TGA Business Services as prior approval is not required.
- If the status code is one of the following, you must obtain prior TGA approval before making the change. Follow the Process to change a registered OTC medicine <https://www.tga.gov.au/publication/process-change-registered-otc-medicine> to apply for approval to make the change.
  - 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.
  - N (notification changes). Application made under subsection 9D(2C) of the Act.
  - A (approvable changes). Application made under subsection 9D(3) or section 23 of the Act.
- If the status code is NEW (new application required), you will need to apply for a new ARTG entry under section 23 of the Act. Follow the OTC medicine registration process <https://www.tga.gov.au/publication/otc-new-medicines-registration-process>.

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 Australian Register of Therapeutic Goods (ARTG) under Section 16(1) of the *Therapeutic Goods Act 1989* (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 <https://www.tga.gov.au/therapeutic-goods-groups-order-no-1-2001> (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 23 of the Act and all require prior TGA approval (most are status code A).

If a new OTC 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 OTC medicine and obtain a new AUST R number.

Determining change codes and application level

It is important that you identify all applicable change codes as you will need these to complete your application and to determine the application level. Each change that requires prior TGA approval corresponds to a particular application level based on risk (CN, C1, C2, C3 or C4).

The regulatory framework underpinning the application levels is described in the Application Categorisation Framework <https://www.tga.gov.au/publication/otc-application-categorisation-framework-0>.

Further information on the notification category is outlined in guidance on the Notifications process: requests to vary registered medicines where quality, safety and efficacy are not affected. /node/

Making more than one change in a single application

If you are making more than one change to your medicine, the application level is determined by the change that attracts highest application level (CN being the lowest level and C4 the highest).

Example

You lodge an application where you change three aspects of the ARTG entry: two C1 level changes and a C3 level change. Submit the application as a C3 level application.

Related guidance

- Determining the correct application level required for OTC medicines submissions

Changes not included in the Changes table

If the change you plan to make is not listed in the Changes table, contact OTC medicines because absence of a code **does not mean** you can make the change to the ARTG record without approval.

If we determine that prior approval is required and none of the change codes in the Changes table are relevant, we will send you an email that:

- endorses the use of the appropriate 'other' change code i.e. OT1 (application level C1), OT2 (application level C2), OT3 (application level C3) or OT4 (application level C4)
  - we will determine the appropriate level for the application based on the principals outlined in the Application Categorisation Framework <https://www.tga.gov.au/publication/otc-application-categorisation-framework-0>.
- advises you of the section of the Act that applies to the change.

In your application, you need to:

- refer to this email in your letter of application (cover letter)
- include our email in module 1.0.

Change table: Labelling (including package insert) and product detail changes

Changes to the labelling including package inserts and product details, including change codes, the change that can be made using this code, the status of the code, the assurance code, the application level for the change and the section of the therapeutic goods act that applies to the change

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: 1. the product name does **not** include an umbrella branded name <https://www.tga.gov.au/publication/otc-application-route-umbrella-branded-medicines> or 2. if it does contain an umbrella branded name <https://www.tga.gov.au/publication/otc-application-route-umbrella-branded-medicines>, then the umbrella segment is not categorised as requiring a higher level of assessment	A	1, 2	C2	23
GPU	Proprietary name (if grouping applies) where: · the product name includes an umbrella branded name <https://www.tga.gov.au/publication/otc-application-route-umbrella-branded-medicines> **and** where 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	C3	23

Change codes	Labelling (including package insert) and product detail changes	Status codes	Assurance codes	Application level	Applicable section of the Act
	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. For example, adding an indication for a 500 mg paracetamol tablet from the list of representative indications in ARGOM's paracetamol guideline	A	1, 3	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. For example, including an indication for a 500 mg paracetamol tablet which is not included in the list of representative indications in ARGOM's paracetamol guideline.	A	1, 3	C4	23
	New therapeutic indications (if grouping doesn't apply)	NEW			
LIW	Therapeutic indications or directions for use - change of wording without altering meaning	A	4, 5	C2	9D(3)
LIS	Therapeutic indications - removal of sub-set of indications from label	SRR	5	C1	9D(2)

Change codes	Labelling (including package insert) and product detail changes	Status codes	Assurance codes	Application level	Applicable section of the Act
LIR	Therapeutic indications - addition of registered indications to label	A	5	C2	9D(3)
GDS	Directions for use - involves a reduction in the class of person for whom the goods are suitable	SRR	5	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. For example, changes to the paediatric dosage recommendations for an ibuprofen oral suspension for infants and children 3 months to 12 years to be consistent with the directions in ARGOM's ibuprofen guideline.	A	1, 3	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. For example, extending the patient population for an ibuprofen oral suspension to include use in neonates.	A	1, 3	C4	23
	Directions for use (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
PSC	Recommended storage conditions - more restrictive	N See notifications guidance	5	CN	9D(2C)
PST	Recommended storage conditions - less restrictive	A	5	C2	9D(3)
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 or an ARGOM warning statement (see also LRA)	SRR	5	C1	9D(2)
LRA	Changes to the label to ensure compliance with RASML other than changes described in LSR	SAR	5	C1	9D(3)
LNT	Changes to bring a label into full compliance with TGO 92 - other than changes to the proprietary name. If changing proprietary name (and where grouping applies), also use code GPN or GPU	A	5	C2	9D(3)

Change codes	Labelling (including package insert) and product detail changes	Status codes	Assurance codes	Application level	Applicable section of the Act
LSF	Changes on label (signal headings, warning statements) in compliance with new SUSMP requirements, where the change in scheduling is from 'Prescription Only Medicine' (Schedule 4) to a lower OTC schedule, except where LSC applies	A	5, 8	C2	9D(3)
LSC	Changes on label (signal headings, warning statements) in compliance with new SUSMP requirements, where the change in scheduling is from 'Prescription Only Medicine' (Schedule 4) to a lower OTC schedule where no such products have previously been approved as an OTC medicine	A	5, 8	C3	9D(3)
LSU	Changes on label (signal headings, warning statements) in compliance with new SUSMP requirements, other than LSF or LSC	SRR/SAR	5, 8	C1	9D(2)/9D(3)
LLR	Addition of a required representation to a label (Part 2 of Schedule 2 to the Therapeutic Goods Regulations)	SRR	5, 7	C1	9D(2)
LCF	Colour, or type size change (no change in label copy), other than where LFT applies	SAR	5	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 See notifications guidance	5	CN	9D(2C)
LGR	Introduction of new graphics/icons (other than as specified in change LSP & KSP)	A	5	C2	9D(3)
RGR	Removal of a graphic (other than as specified in change LAB for removal of sponsor logo or RGN)	SAR	5	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 See notifications guidance	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	C1	9D(3)

Change codes	Labelling (including package insert) and product detail changes	Status codes	Assurance codes	Application level	Applicable section of the Act
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 See notifications guidance	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 See notifications guidance	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	C1	9D(3)
LDT	Deletion or addition of text to the label (including rewording of pre-existing text) where there is no requirement for supporting module 4 and/or module 5 data (may entail the provision of quality data such as dissolution data to support a 'fast' claim), other than as specified in change LAB	A	5	C2	9D(3)

Change codes	Labelling (including package insert) and product detail changes	Status codes	Assurance codes	Application level	Applicable section of the Act
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	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	C2	9D(3)
KPD	Introduction of a package insert where supporting module 4 and/or module 5 data or a justification for not providing the supporting data is required. For example, inclusion of a package insert with a section on absorption based on module 5 data which includes claims pertaining to *'fast'* absorption.	A	5, 29	C3	9D(3)
KRI	Removal of a package insert	A	5, 30	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 See notifications guidance	5	CN	9D(2C)

Change codes	Labelling (including package insert) and product detail changes	Status codes	Assurance codes	Application level	Applicable section of the Act
	Changes to package insert: since the package insert is treated as part of the label, select the appropriate change code(s) from the *'Labelling (including package insert) and product detail changes'* section of the Changes Table				
LAB	Minor label editorials that have no regulatory compliance impact (under the *Therapeutic Goods Act 1989*). 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 · inclusion, removal or changes to: 1. 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) 2. sponsor address and/or contact details provided the	0			

Change codes	Labelling (including package insert) and product detail changes	Status codes	Assurance codes	Application level	Applicable section of the Act
	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 3. 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 4. date of manufacture of a product 5. 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 the TGA for that product 6. ABN/ACN 7. product code number (or equivalent) or an overseas registration number 8. recycle logo and associated text 9. tamper evident seal - wording/graphics. See also KSL and KSX 10. trade mark (™) or registration (®) symbols or similar or trademark statements e.g. Company XXY is a registered trademark of Company XXZ 11. introduction, deletion or change of a graphic and/or text providing instruction on opening or closing a container 12. anti-theft device (including directly associated wording) that				

Change codes	Labelling (including package insert) and product detail changes	Status codes	Assurance codes	Application level	Applicable section of the Act
	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	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 See notifications guidance	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	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 See notifications guidance	5, 6, 10, 13	CN	9D(2C)
PMZ	Addition of pack size – for metered dose aerosols	A	5	C2	9D(3)

Change codes	Labelling (including package insert) and product detail changes	Status codes	Assurance codes	Application level	Applicable section of the Act
PSD	Pack size – deletion	N See notifications guidance	5	CN	9D(2C)
	Dosage form (as defined in TGA Approved Terminology for Medicines)	NEW			
PVI	Visual identification	SAR	5, 13, 19, 27	C1	9D(3)
PSL	Shelf life - increase (other than in change PSP)	A	5	C2	9D(3)
PSR	Shelf life - decrease	N See notifications guidance	5	CN	9D(2C)
PSP	Shelf life - increase, where this is in accordance with a TGA approved protocol for self assessable shelf life extensions for that particular product (refer ARGOM Appendix 2, section 9.10 & 9.10.1 <https://www.tga.gov.au/publication/argom-appendix-2-guidelines-quality-aspects-otc-applications>)	SAR	5, 11, 20	C1	9D(3)

Change codes	Labelling (including package insert) and product detail changes	Status codes	Assurance codes	Application level	Applicable section of the Act
PPR	Request for a stability testing protocol for self assessable shelf life extensions for a specific product (refer ARGOM Appendix 2, section 9.10 <https://www.tga.gov.au/book-page/9-stability-finished-product#s910>)	A	5	C2	9D(3)
PMI	Sterility status	A	5	C2	9D(3)

Change table: Sponsor changes

For the transfer of a good in the ARTG from one sponsor to another contact the eBS help desk or see Notification of a change of sponsorship <https://www.tga.gov.au/form/notification-change-sponsorship-0>.

NB. For changes to sponsor details on the labelling see LAB and LSP; for changes to sponsor details in the PI see DAB and DAC.

Change table: Formulation changes - active ingredients

Changes to the formulation of the active ingredient, including change codes, the change that can be made using this code, the status of the code, the assurance code, the application level for the change and the section of the therapeutic goods act that applies to the change

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			
	Amount of an active ingredient - see also *'Overages and ranges'* in ARGOM Appendix 2, section 4.1 <https://www.tga.gov.au/book-page/4-development-pharmaceutics-and-formulation#s41>	NEW			
AOV	Overage - decrease or removal	N See notifications guidance	5	CN	9D(2C)
AOA	Overage - increase	A	5	C2	9D(3)

Change codes	Formulation changes - active ingredients	Status codes	Assurance codes	Application level	Applicable section of the Act
GPA	Replacement of a proprietary ingredient which 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 an excipient(s) ingredient (if grouping applies)	A	1, 5	C2	23
	Replacement of a proprietary ingredient which contains an active ingredient with another proprietary ingredient, other than as above in change GPA	NEW			

Change table: Formulation changes - excipient ingredients

Changes to the formulation of excipient ingredients, including change codes, the change that can be made using this code, the status of the code, the assurance code, the application level for the change and the section of the therapeutic goods act that applies to the change

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	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	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 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	A	1, 5, 13	C2	23

Change codes	Formulation changes - excipient ingredients	Status codes	Assurance codes	Application level	Applicable section of the Act
	or GPI				
	The replacement of one proprietary ingredient with a different proprietary ingredient other than GPI or GPR	NEW			
	Addition or deletion of an excipient other than those above in change GPI	NEW			
GEX	Amount of excipient (if grouping applies) provided the content of the excipient is not higher than previously approved for the dosage form - if unsure, contact otc.medicines@tga.gov.au See also *'Batch to batch variations in quantities of certain excipients'* ARGOM Appendix 2, section 5.3 <https://www.tga.gov.au/book-page/5-manufacture-medicine#s53>	A	1, 5, 13	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 - if unsure, contact otc.medicines@tga.gov.au See also *'Batch to batch variations in quantities of certain excipients'* ARGOM Appendix 2, section 5.3 <https://www.tga.gov.au/book-page/5-manufacture-medicine#s53>	A	1, 5, 13	C3	23

Change codes	Formulation changes - excipient ingredients	Status codes	Assurance codes	Application level	Applicable section of the Act
	Amount of excipient (if grouping doesn't apply) – see also *'Batch to batch variations in quantities of certain excipients'* ARGOM Appendix 2, section 5.3 <https://www.tga.gov.au/book-page/5-manufacture-medicine#s53>	NEW			
EST	Type of starch (no change to quantity)	N See notifications guidance	5, 12	CN	9D(2C)

Change table: Quality control changes - finished product specifications

Changes to the quality controls for finished product specifications, including change codes, the change that can be made using this code, the status of the code, the assurance code, the application level for the change and the section of the therapeutic goods act that applies to the change

Change codes	Quality control changes - finished product 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	C2	9D(3)
QFF	Specification limits or requirements - less restrictive; where supporting module 4 (preclinical/toxicological) 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	C3	9D(3)
QFT	Addition of an extra test	O			
QFU	Deletion of an existing test where any supporting data provided consist only of module 3 data	A	5, 27	C2	9D(3)

Change codes	Quality control changes - finished product specifications	Status codes	Assurance codes	Application level	Applicable section of the Act
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	C3	9D(3)
QFI	Frequency of testing - increase	O			
QFR	Frequency of testing - reduction	A	5, 27	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 *Therapeutic Goods Act 1989* (e.g. the BP or a Therapeutic Goods Order), other than as specified in change MST. No non-pharmacopoeial test/requirement is concurrently deleted from the specification.	O			
QFB	Analytical method (does not include changes to tests and limits/requirements) - which has been demonstrated to maintain or improve analytical performance (accuracy, precision and/or specificity), other than as specified in change MST	O			
QFC	Analytical method - other than as specified in change QFA, QFB or MST	A	5	C2	9D(3)

Change codes	Quality control changes - finished product specifications	Status codes	Assurance codes	Application level	Applicable section of the Act
QFP	Change from one default standard (as defined in the *Therapeutic Goods Act 1989*) 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 See notifications guidance	5, 27	CN	9D(2C)

Change table: Quality control changes - starting material specifications

Changes to the quality controls for the starting materials specifications, including change codes, the change that can be made using this code, the status of the code, the assurance code, the application level for the change and the section of the therapeutic goods act that applies to the change

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	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	C3	9D(3)
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	C2	9D(3)

Change codes	Quality control changes - starting material specifications	Status codes	Assurance codes	Application level	Applicable section of the Act
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 which support the sponsor's case for removal of the test from the specifications.	A	5, 27	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 *Therapeutic Goods Act 1989* <https://www.legislation.gov.au/Series/C2004A03952> (e.g. the BP or a Therapeutic Goods Order). No non-pharmacopoeial test/requirement is concurrently deleted from the specification e.g. a specification for particle size distribution.	O			
QSB	Analytical method (does not include changes to test limits/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	C2	9D(3)
QSM	Manufacturer of starting material (specifications unchanged)	O			

Change codes	Quality control changes - starting material specifications	Status codes	Assurance codes	Application level	Applicable section of the Act
QSS	Supplier of starting material	O			
QSP	Change from one 'default standard' (as defined in the *Therapeutic Goods Act 1989* <https://www.legislation.gov.au/Series/C2004A03952>) 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 See notifications guidance	5	CN	9D(2C)

Change table: Packaging changes

Changes to the packaging for OTC medicines, including change codes, the change that can be made using this code, the status of the code, the assurance code, the application level for the change and the section of the therapeutic goods act that applies to the change

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 <https://www.tga.gov.au/publication/tga-approved-terminology-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: a. Polystyrene to PVC, polyethylene, polypropylene or glass; b. PVC to polyethylene, polypropylene or glass; c. Polyethylene to glass or polypropylene of density ≥ 0.89; d. From one density of polyethylene to a higher density; or e. Any change between glass, polyethylene of density ≥ 0.95, and polypropylene of density ≥ 0.89.	N See notifications guidance	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: a. PVC to PVC/PVDC or to PVC/PCTFE; b. 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 See notifications guidance	5, 13 & 25	CN	9D(2C)
KCI	Container - increase in container wall thickness	O			
KCT	Container - decrease in container wall thickness where the decrease in thickness is not considered to increase permeability of the container (e.g. a decrease in the wall thickness of a glass bottle) and where stability testing will continue for the full term of the products' shelf life and the TGA advised immediately of any batches not meeting specification.	O			
KCD	Container - decrease in container wall thickness, except where KBT, KBL or KCT apply	A	5	C2	9D(3)

Change codes	Packaging changes	Status codes	Assurance codes	Application level	Applicable section of the Act
KOT	Container material-other than in changes KBT, KGL, KBL, KCI, KCD or KCT	A	5	C2	9D(3)
KCL	Closure - other than changes in KCM or MDA	N See notifications guidance	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			

Change codes	Packaging changes	Status codes	Assurance codes	Application level	Applicable section of the Act
KDA	Desiccant - inclusion in container	A	5	C2	9D(3)
KDX	Desiccant - removal from container	A	5	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 & proposed label must be supplied if the label is changed	SAR	5, 24	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 & proposed label must be supplied if the label is changed.	N See notifications guidance	5	CN	9D(2C)

Change codes	Packaging changes	Status codes	Assurance codes	Application level	Applicable section of the Act
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 & proposed label must be supplied if the label is changed.	SAR	5, 24	C1	9D(3)
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	C1	9D(3)
KPX	Removal of a primary pack	SAR	5, 17	C1	9D(3)
KRP	Introduction of a refill pack	A	5	C2	9D(3)
KRR	Removal of refill pack	N See notifications guidance	5	CN	9D(2C)

Change table: Manufacturing changes - finished product

Manufacturing changes to the finished product, including change codes, the change that can be made using this code, the status of the code, the assurance code, the application level for the change and the section of the therapeutic goods act that applies to the change

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 See notifications guidance	5, 9	CN	9D(2C)
MMD	Deletion of a manufacturer (includes site of manufacture).	N See notifications guidance	5	CN	9D(2C)
AMS	Addition of steps of manufacture, other than for sterile products where MSS or MST applies	N See notifications guidance	5	CN	9D(2C)
MSD	Deletion of steps of manufacture.	N See notifications	5	CN	9D(2C)

Change codes	Manufacturing changes - finished product	Status codes	Assurance codes	Application level	Applicable section of the Act
		guidance			
MPT	Manufacturing process: tightening of in-process limits and/or introduction of an additional in-process control	O			
MPR	Manufacturing process other than for 'higher risk' OTC products (see MPH or MPD) or for sterile products (see MSS or MST). See also MPT	SAR	5, 13	C1	9D(3)
MPH	Manufacturing process for the following 'higher risk' OTC products: · microdose products (solid oral dosage forms where the active ingredient is present in an amount of less than 2mg or 2% w/w of the dosage form) · products with a sustained release characteristic (not including enteric coated products) · metered dose inhalers · nasal corticosteroids where the changes have been demonstrated, for the product, to be equivalent to or superior to the approved manufacturing process	SAR	5, 13	C1	9D(3)
MPD	Manufacturing process for the following 'higher risk' OTC	A	5, 13	C2	9D(3)

Change codes	Manufacturing changes - finished product	Status codes	Assurance codes	Application level	Applicable section of the Act
	products: · microdose products (solid oral dosage forms where the active ingredient is present in an amount of less than 2mg or 2% w/w of the dosage form) · products with a sustained release characteristic (not including enteric coated products) · metered dose inhalers · nasal corticosteroids except where MPH applies. See also *'Manufacturing process validation'* in ARGOM Appendix 2, section 5.2.1 <https://www.tga.gov.au/book-page/5-manufacture-medicine#s521>				
MUP	GMP clearance number update only. Involves no other change to the product	SAR (fee exempt)	5	C1	9D(3)
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	N See notifications guidance	5, 9	CN	9D(2C)

Change codes	Manufacturing changes - finished product	Status codes	Assurance codes	Application level	Applicable section of the Act
	of the following steps: release for supply, secondary packaging or testing [chemical and physical or microbial]				
MST	For a sterile product: 1. Addition of a manufacturer (includes site of manufacture) other than where MSS applies 2. Addition of steps of manufacture other than where MSS applies 3. Change in the manufacturing process (see also *'Manufacturing process validation'* in ARGOM Appendix 2, section 5.2.1 <https://www.tga.gov.au/book-page/5-manufacture-medicine#s521>)	A	5	C2	9D(3)

Change table: Consumer Medicine Information (CMI)

Changes to consumer medicine information, including change codes, the change that can be made using this code, the status of the code, the assurance code, the application level for the change and the section of the therapeutic goods act that applies to the change

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 and is not to be included as a package insert. Note: Change KPI or KPD applies where the CMI is to be included as a package insert.	O			
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 the *Labelling (including package insert) and product detail changes* section for guidance 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			

Change table: Product Information (PI)

Changes to product information, including change codes, the change that can be made using this code, the status of the code, the assurance code, the application level for the change and the section of the therapeutic goods act that applies to the change

Change codes	Product Information (PI)	Status codes	Assurance codes	Application level	Applicable section of the Act
DPI	Introduction of a 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 product.	A	5	C2	9D(3)
DPD	Introduction of a 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	C3	9D(3)
DAB	Minor editorial changes that have no regulatory compliance impact (under the *Therapeutic Goods Act 1989*). 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:	O			

Change codes	Product Information (PI)	Status codes	Assurance codes	Application level	Applicable section of the Act
	1. country of origin statement (e.g. 'Made in XX') 2. 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 3. supplier/manufacturer name, address and/or contact details 4. ABN/ACN 5. product code number (or equivalent) or an overseas registration number 6. 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: 1. storage conditions 2. sponsor details including sponsor name and/or logo (inclusion of a logo or change of an existing logo) except where DAB applies 3. container or pack size details 4. visual identification	SAR	5	C1	9D(3)

Change codes	Product Information (PI)	Status codes	Assurance codes	Application level	Applicable section of the Act
	5. dosage form 6. route of administration 7. formulation details 8. poisons schedule 9. proprietary name 10. indications (where the wording is identical to that included on the ARTG or that proposed for the ARTG as part of the same application) Does not include changes to the directions for use				
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 an ARGOM warning statement (See also LSR for consequential changes to labelling)	SRR	5	C1	9D(2)

Change codes	Product Information (PI)	Status codes	Assurance codes	Application level	Applicable section of the Act
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	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	C3	9D(3)
DRP	Removal of a PI where the PI is not required under section 25AA of the Act. For example, removal of a PI for an unscheduled paracetamol 500 mg tablet.	A	5	C2	9D(3)

Change table: Other

Other changes to OTC medicines, including change codes, the change that can be made using this code, the status of the code, the assurance code, the application level for the change and the section of the therapeutic goods act that applies to the change

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 *Therapeutic Goods Act 1989*. Evidence to support the change is included with the application	SAR	5, 21	C1	9D(1)
CAO	Correction of ARTG record in accordance with section 9D(1) of the *Therapeutic Goods Act 1989*. 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	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	ASK	31	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	C2	Specified in advice from TGA
OT3	'Other' changes - application level C3. An 'other' code is used only	ASK	31	C3	Specified in advice

Change codes	Other	Status codes	Assurance codes	Application level	Applicable section of the Act
	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				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	C4	Specified in advice from TGA
IHN	Update of ingredient name/s on labelling/Product Information in accordance with the TGA's International Harmonisation of Ingredient Names (IHIN) project.	SAR (Fee Exempt)	5	C1	9D(1)

Status codes

Status codes relating to the type of application needed to make a change to a registered OTC medicine, including the status code, whether TGA approval is needed before the change can be made and the type of application needed either an application for an new ARTG entry or to change the existing entry

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. Nb. 1. Change codes for 'O' status changes are not included in the application portal. Nb. 2. Changes with status 'O' have been included for clarity and completeness and do not imply that this information is required for evaluation of an equivalent new product.

Code	Prior TGA approval required?	Description
ASK	Yes	This applies only where one of the 'other' change codes (OT1, OT2, OT3 or OT4) is used. Refer to the Changes not included in the Changes Table for guidance.

Assurance codes

Assurances code relating to the assurances that need to be made for the types of changes to be made to an OTC registered medicine, including the code and the assurance the sponsor needs to make regarding the change to be made.

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).
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.

Code	Description
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 which 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.
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.	1. Neither the existing nor the new material is a modified starch; and 2. The changeover has been validated; and 3. 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; and 4. 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.

Code	Description
13.	1. The changeover has been validated* and the Sponsor is satisfied that the change will not adversely affect the stability of the product; and 2. 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 (also see Guidelines on quality aspects of OTC applications <https://www.tga.gov.au/publication/argom-appendix-2-guidelines-quality-aspects-otc-applications>)
14.	No new text or graphics have been introduced.
15.	This code is 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.	This code is intentionally blank.
19.	Manufacturing method and specifications, other than visual identification, have not been changed.

Code	Description
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 s9D(1) of the Act.
22	This code is intentionally blank.
23	This code is 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	This code is intentionally blank.
27	A copy of the current specification plus a copy of the new specification, with the changes highlighted, have been supplied.
28	This code is intentionally blank.

Code	Description
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 the TGA advising the use of this change code for the requested change to the product has been supplied.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	OTC Medicines Regulatory Guidance	15 April 2013
V1.1	Clarified requirement for analytical validation summary forms and included hyperlink Clarified requirement for applications to be in common technical document (CTD) format Included reference to 'different strength or size' in the Groups Order - Summary section Changed references from SUSDP to SUSMP Added new change codes (previously referred to as TBD)	OTC Medicines Regulatory Guidance	15 April 2013
V2.0	Guidance reformatted, restructured and redrafted as web pages Added new codes (identified in the tables as NEW) Removed duplicated and redundant change codes and consolidated other change codes for clarity Amended change codes to include examples where necessary Combined the 'Label changes (including package insert)' and 'Product detail changes' sections Updated the 'Assurance codes' table and updated the assurance codes within the Changes Table accordingly	OTC CMB and Regulatory guidance team	30 November 2015
V2.1	Add new code – IHN	Management & Operations Section, Complementary and OTC Medicines Branch	13 September 2016

Version	Description of change	Author	Effective date
V2.2	Addition of two new codes (identified in table as New), amendment of an existing code (identified in table as Amended) and deletion of a redundant code (LLO)	OTC Medicines Evaluation and Management & Operations Section, COMB	3 February 2017
V2.3	Update to change codes (PSC, LLN, LSP, PSR, AOV, EST, QFP, QSP, KBT, KBL, KCL, KRR, MMA, MMD, AMS, MSD) to reflect the new notification process commencing 1 July 2017.	OTC Medicines Evaluation Section / Scientific Operations Management Section	30 June 2017
V2.4	Update to change codes to include further notifications, commencing 4 December 2017.	OTC Medicines Evaluation Section / Scientific Operations Management Section	4 December 2017

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R16/280522