Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Guidelines on changes to OTC medicines

Australian regulatory guideline for over-the-counter medicines

Version 1.1, April 2013

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <www.tga.gov.au>.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	OMA – OTCME	15/04/2013
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)	OMA – OTCME	15/04/2013

Contents

Introduction

This interim guideline on changes to OTC medicines is based largely on ARGOM's *Changes to OTC medicines* (version 1.3 published October 2012). It has been updated to accommodate the new process for the pre-market evaluation of OTC medicines in Australia. The guideline will be updated and revised as needed throughout the staged implementation of the new process.

Where the sponsor of a registered OTC medicine wishes to make a change to the product, it is a condition of registration (under Section 28 of the *Therapeutic Goods Act 1989* (the 'Act')) that, with limited exceptions, the change(s) requires prior TGA approval.

The 'Changes Table' provides guidance on the types of application required when a sponsor wishes to change the details of their registered OTC medicine. With the exception of changes requiring a 'new' application, the selection of a 'change code' will be linked to an application level - C1, C2, C3, or C4. This will determine the level of the application.

Where more than one change type is being proposed within a single application, the application level is determined by the highest application level (with C1 being the lowest level and C4 the highest).

What if the proposed change is not in the Changes Table?

If the proposed change is not described in the Changes Table, contact the staff of the OTC Medicines Evaluation Section. The absence of the proposed change from the Changes Table does not imply that the sponsor may proceed without requesting prior approval from the TGA.

If it is determined, following consultation with the OTC Medicines Evaluation Section, that none of the specific change codes are relevant to the proposed change, then the change code 'OTH' (other) will be used. The OTC Medicines Evaluation section will provide written confirmation to the sponsor, typically in the form of an email, endorsing the use of the 'OTH' change code and advising the application level (C1-C4) appropriate for the particular change. The application level will be determined in accordance with the *OTC application categorisation framework* for changes to approved medicines.

In general, if the proposed change is a quality related change or a change to the labelling that doesn't require the provision of safety or efficacy data, the application level is likely to either be C1 or C2. If the proposed change relates to the labelling or other product documentation (such as the product information) and it requires supporting safety or efficacy data but is not a change involving a new indication or directions for use, then it is likely to be in C3.

Written advice from the TGA confirming use of the OTH change code must be included with the application as an attachment to the cover letter and should be explicitly referred to in the cover letter.

Does the change make the therapeutic goods 'separate and distinct'?

Some changes may render the changed therapeutic goods *separate and distinct* from the present goods. Section 16 of the Act lists those criteria which make goods *separate and distinct*.

Where the Therapeutic Goods (Groups) Order (the 'Groups Order') applies, the sponsor of an OTC medicine can replace the existing product in the ARTG with a new OTC medicine. An example of this is when a sponsor changes the name of an existing OTC medicine in the ARTG. For a summary of the provisions of the Therapeutic Goods (Groups) Order, refer to the Groups Order—summary.

However, if a new OTC medicine is *separate and distinct* from the existing medicine and the Groups Order does **not** apply, the sponsor will need to submit a new application for registration of the medicine.

Applications to register *separate and distinct* OTC medicines (regardless of whether the Groups Order applies or not) do so under the provisions of Section 23 of the Act.

What data / information do I need to include with my application?

Once the sponsor has identified the correct application level for their application (refer *Pre-market application and evaluation process*), the sponsor can then refer to the *OTC dossier documents matrix* and appendices 1–5 of ARGOM to ascertain the data requirements for their application. Applications which include new or changed analytical procedures and associated validation data also need to include completed OTC analytical validation summary forms.

Submitting the application

Applications are submitted in the common technical document (CTD) format through the electronic business services (eBS) portal. The sponsor should refer to *Pre-market application and evaluation process*, the *OTC dossier document matrix* and to appendices 1–5 of ARGOM to ascertain the applicable data requirements for the application.

Other aspects of the product (that are not being changed)

Generally, only the requested change(s) will be reviewed at the time of application. However, some changes naturally impact on other aspects of the product which may require further clarification. If a problem is detected which is unrelated to the requested change, it may be followed up as a separate issue, but will generally not hold up processing of the application.

Sponsors should be aware that sometimes a proposed change might involve additional consequential changes (e.g. removal of a colouring agent may also require change to visual identification). In such cases, each of the relevant changes should be specified in the application.

The same change for many products?

A sponsor can submit an application to make an identical change(s) to multiple OTC products. This type of application applies only when the change does not require separate assessment for individual products or when there is no change unique to one particular product within the group that requires separate assessment.

An example of an acceptable application of this type is where a sponsor requests a change to the same principal licensed manufacturer for a range of registered products. However, if the sponsor wants to make an additional change to one out of the group of products (e.g. the addition of an additional Australian manufacturing site), then that product should not be included with the multiple change application. The changes for that product should be submitted as a standalone application.

Each ARTG entry included in the application must contain current and complete details for the entire submission to pass validation in eBS. If the application fails validation, then the ARTG entries require individual updating through eBS to include the new change(s) and correct the records. Individual applications require individual payment of the relevant fees for each submission made to the TGA.

Sponsors of applications involving more than one product should submit separate, individual product-specific copies of the relevant supporting documents for each Australian Registration (AUST R) number that the change applies to, for product-specific record-keeping purposes.

Applications involving 'Groupable' changes cannot be submitted as part of an application involving more than one product; 'Groupable' changes require a separate application (see 'Groups Order—summary') for each product.

Change to an entry in the ARTG

Section 9D of the Act refers to how the Secretary (or Secretary's Delegate, the 'Delegate') may vary entries in the ARTG.

Applications for changes to medicines that require minimal assessment by the Delegate are denoted by the 'Status Codes' "SRR" (safety related request) or "SAR" (self assessable request) in the Changes Table. The Safety Related Requests (SRR) are approved by the Delegate under section 9D(2) of the Act; the Self Assessable Requests (SAR) are approved by the Delegate under section 9D(1) or section 9D(3) of the Act. These types of changes are included in application level C1 and only require the payment of an application fee and do not require payment of evaluation fees.

All other changes denoted by 'A' as the status code in the Changes Table made under Section 9D of the Act require significant assessment by the Delegate and therefore require payment of evaluation fees as well as application fees. The applications for some change types denoted by 'A' as the status code are made under section 23 of the Act.

All applications under section 9D or section 23 of the Act require approval before the sponsor can proceed with the change. Should the application be unsuccessful, the TGA will provide a rejection letter which contains details of procedures for review of the decision.

Groups Order—summary

The 'Groups Order' specifies the circumstances in which a 'separate and distinct' therapeutic good can be 'grouped' in the same ARTG entry (i.e. under the same AUST R number). In this case, a new OTC medicine can replace the existing product in the ARTG. The Groups Order explains when this is acceptable.

Section 16 of the Act sets out the criteria which make goods 'separate and distinct'. These are:

- a different name or
- different indications or
- different directions for use or
- a different type of container or
- a different dosage form or
- a different formulation or composition or
- a different strength or size (disregarding pack size).

When the Groups Order does not apply, the changed goods must have a separate ARTG entry and bear a separate AUST R number. If this is the case, the sponsor should apply for registration of the changed goods as if it were an entirely new product.

The provisions of the Groups Order (as applied to non-prescription medicines) may be summarised as follows.

Name change

Goods may be grouped when the only difference between the new goods and the existing goods is the proprietary name and when the new goods are to replace the existing goods in use.

Change in the amount of an excipient

Goods may be grouped when the formulation of the new goods is to be changed only by increasing or decreasing the amount of an excipient (but not adding or deleting an excipient) and when the new goods are to replace the existing goods in use.

Removal or addition of a fragrance, flavour, printing ink or colour

Goods may be grouped when the formulation is changed only by the addition or removal of a fragrance, flavour, printing ink or colouring agent and when the new goods are to be registered in place of the existing goods.

Revised indications and/or directions for use

Goods may be grouped when only the indications and/or directions for use are changed and the new goods are to be registered in place of the existing goods.

Changes Table—codes

Sponsors must select a change code(s) from the Changes Table which describes the proposed change(s) to the medicine. More than one change code can be selected in an application. Selecting these codes will determine the assurances required and the application level (C1–C4) applicable for the selected change.

It is the responsibility of the sponsor to ensure the accurate selection of the change codes so that the assurances and application level categories pertaining to each change code are correct.

Where a description of the proposed change cannot be found in the Changes Table, contact the staff of the OTC Medicines Evaluation section (refer What if the proposed change is not in the Changes Table?).

Status codes

The status codes appear in the Changes Table to provide sponsors with simple guidance on the type of application required when changing their existing good.

Code	Description
A	An approvable change made under section 9D or section 23 of the Act.
SRR	Safety Related Request: an approvable change made under section 9D(2) of the Act.
SAR	Self Assessable Request: an approvable change made under section 9D(1) or section 9D(3) of the Act.
NEW	New application for registration required.
O	No prior approval required. Changes with status 'O' have been included for completeness and do not imply that this information is required for evaluation of an equivalent new product
ASK	This applies only where the 'OTH' (other) change code is used. The sponsor must contact the OTC Medicines Evaluation section before submitting an application with this change code (refer What if the proposed change is not in the Changes Table?).

Documentation and assurance codes

Code	Description
E	Evidence to support the change where an ARTG entry is to be corrected.
L	A copy of the current label of the goods plus a draft copy of the new label, with the relevant changes highlighted have been supplied.
PI	A copy of the current Product Information (PI) of the goods plus a draft copy of the new PI, with the relevant changes highlighted, have been supplied.
P	The *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) schedule level for the new pack size(s) has been selected on the application form.
1.	The 'new' goods are intended to replace the existing goods in use.

Code	Description
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.
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.	a. Neither the existing nor the new material is a modified starch; and b. The changeover has been validated; and c. 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 d. 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 Office of Medicines Authorisation.

Code	Description
13.	a. The changeover has been validated* and the Sponsor is satisfied that the change will not adversely affect the stability of the product; and b. 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 ARGOM Appendix 2 *Guidelines on quality aspects of OTC medicines*).
14.	No new text or graphics have been introduced.
15.	The change of material is one of the following: 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.
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.	The change to the plastic component is one of the following: 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*').
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.

Changes Table

Label changes (including package insert)

Change codes	Label changes (including package insert)	Status	A/D*	Appln level	Applicable section of the Act
GPN	Proprietary name (if grouping applies) where: 1. the product name does **not** include an umbrella branded name or 2. 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, L	C2	23
GPU	Proprietary name (if grouping applies) where the product name includes an umbrella branded name **and** where the umbrella segment is categorised as requiring a higher level of assessment	A	1, 2, L	C3	23
	Proprietary name (if grouping doesn't apply)	NEW			
GIN	New therapeutic indications (if grouping applies) where there is no requirement for supporting data	A	1, 3, L	C2	23
GID	New therapeutic indications (if grouping applies) where supporting data or a justification for not providing supporting data is required	A	1, 3, L	C4	23

Change codes	Label changes (including package insert)	Status	A/D*	Appln level	Applicable section of the Act
	New therapeutic indications (if grouping doesn't apply)	NEW			
LIW	Therapeutic indications or directions for use—change of wording without altering meaning	A	4, L	C2	9D(3)
LIS	Therapeutic indications—removal of sub-set of indications from label	SRR	5, L	C1	9D(2)
LIR	Therapeutic indications—addition of registered indications to label	A	5, L	C2	9D(3)
GDU	Directions for use—e.g. dosage instructions (if grouping applies) where there is no requirement for supporting data. (See also LIW)	A	1, 3, L	C2	23
GDD	Directions for use—e.g. dosage instructions (if grouping applies) where supporting data or a justification for not providing supporting data is required. (See also LIW)	A	1, 3, L	C4	23
	Directions for use (if grouping doesn't apply)	NEW			
PSC	Recommended storage conditions—more restrictive	SAR	5	C1	9D(3)
PST	Recommended storage conditions—less restrictive	A	-	C2	9D(3)
LSR	Addition of more restrictive safety-related statements	SRR	5, L	C1	9D(2)

Change codes	Label changes (including package insert)	Status	A/D*	Appln 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 schedule	A	-	C2	9D(2) / 9D(3)
LSU	Changes on label (signal headings, warning statements) in compliance with new SUSMP requirements, other than LSF	SRR / SAR	5, 8, L	C1	9D(2) / 9D(3)
LLO	Changes to bring a label into compliance with the Labelling Order—other than changes to the proprietary name, indications or directions for use	SRR / SAR	5, 7, L	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, L	C1	9D(2)
LCF	Colour, font, type size only (no change in label copy)	SAR	5, L	C1	9D(3)
LGR	Introduction of new graphics/icons (other than as specified in change SSP & KSP)	A	-	C2	9D(3)
RGR	Removal of a graphic (other than as specified in change SSP)	SAR	5, L	C1	9D(3)
LFO	Reformatting of pre-existing text (ie moving of blocks of text and not rewording—see LIW, LRT)	SAR	5, L	C1	9D(3)

Change codes	Label changes (including package insert)	Status	A/D*	Appln level	Applicable section of the Act
LRT	Rewording of pre-existing text without altering meaning (other than indications or directions for use—see LIW)	A	-	C2	9D(3)
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.) where there is no requirement for supporting data	A	-	C2	9D(3)
LDD	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.) where supporting data or a justification for not providing supporting data is required	A	-	C3	9D(3)
COO	Addition or deletion of a country of origin statement e.g. 'Made in xx'	SAR	5, L	C1	9D(3)

Sponsor changes

Change codes	Sponsor changes	Status	A/D*	Appln level	Applicable section of the Act
SSP	Sponsor name/logo/sponsor address (same sponsor of goods) and/or change to manufacturer/supplier details on label	SAR	5, L	C1	9D(3)

Product detail changes

Change codes	Product detail changes	Status	A/D*	Appln level	Applicable section of the Act
PSZ	Pack size—other than liquids/semi-solids (see PLS) or metered dose aerosols (see PMZ) (see also KBT, KGL, KBL and KOT)	SAR	5, 6, 10, L, P	C1	9D(3)
PLS	Pack size—liquids/semi-solids	SAR	5, 6, 10, 13, L, P	C1	9D(3)
PMZ	Pack size—metered dose aerosols	A	-	C2	9D(3)
	Dosage form (as defined in *TGA Approved Terminology for Medicines*)	NEW			

Change codes	Product detail changes	Status	A/D*	Appln level	Applicable section of the Act
PVI	Visual identification	SAR	5, 13, 19	C1	9D(3)
PSL	Shelf life—increase (other than in change PSP)	A	-	C2	9D(3)
PSR	Shelf life—decrease	SAR	5	C1	9D(3)
PSP	Shelf life—increase (in accordance with an approved stability testing protocol for that product)	SAR	5, 11, 20	C1	9D(3)
PPR	Approval of a stability testing protocol for a specific product	A	-	C2	9D(3)
PSC	Recommended storage conditions—more restrictive	SAR	5	C1	9D(3)
PST	Recommended storage conditions—less restrictive	A	-	C2	9D(3)
PMI	Sterility status/technique	A	-	C2	9D(3)

Formulation changes—active ingredients

Change codes	Formulation changes—active ingredients	Status	A / L*	Appln 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	NEW			
AOV	Overage—decrease	SAR	5	C1	9D(3)
AOA	Overage—increase	A	-	C2	9D(3)
GPA	Change to amount of an excipient ingredient within a proprietary ingredient which contains an active substance (e.g. a direct-compression paracetamol mix) (if grouping applies)	A	1	C2	23
	Change to a proprietary ingredient which contains an active ingredient, other than as above in change GPA	NEW			

Formulation changes—excipient ingredients

Change codes	Formulation changes— excipient ingredients	Status	A / L*	Appln level	Applicable section of the Act
GPI	Removal and/or addition of a fragrance, flavour, printing ink or colouring agent (if grouping applies), other than change ERT	A	1, 13	C2	23
	Removal or addition of a fragrance, flavour, printing ink or colouring agent (if grouping doesn't apply)	NEW			
ERT	Removal of 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 (eg. deletion from the label of declared ingredients that are no longer relevant; change to visual identification and finished product specifications) which should also be addressed in accordance with the 'Changes Table'.	SAR	5	C1	23
	Addition of excipient other than those above in change GPI	NEW			
	Deletion of excipient other than those above in change GPI	NEW			
GEX	Amount of excipient (if grouping applies)	A	1	C2	23

Change codes	Formulation changes— excipient ingredients	Status	A/D*	Appln 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	NEW			
EST	Type of starch	SAR	5, 12	C1	9D(3)
EWI	Change to ingredients within a proprietary ingredient which is a flavour, fragrance, printing ink or colour (proprietary ingredient has same name)	SAR	5, 13	C1	9D(3)
EWA	Change to ingredients within a proprietary ingredient which is an excipient (other than above in change EWI)	A	-	C2	9D(3)

Quality control changes—finished product specifications

Change codes	Quality control changes—finished product specifications	Status	A/D*	Appln level	Applicable section of the Act
QFX	Specification ranges—more restrictive	O			
QFE	Specification ranges—less restrictive	A	-	C2	9D(3)

Change codes	Quality control changes—finished product specifications	Status	A/D*	Appln level	Applicable section of the Act
QFT	Addition of an extra test	O	-		
QFU	Deletion of an existing test	A	-	C2	9D(3)
QFA	Analytical method—to comply with amendments to a standard (e.g. the BP or a Therapeutic Goods Order)	O			
QFB	Analytical method—which has been demonstrated to maintain or improve analytical performance (accuracy, precision and/or specificity)	O			
QFC	Analytical method—other than as specified above in change QFB	A	-	C2	9D(3)
QFS	Expiry specification ranges following changes to the BP or the General standard for tablets pills and capsules or changes to the USP where a USP monograph has been approved by the TGA in relation to the product	O			

Quality control changes—starting material specifications

Change codes	Quality control changes— starting material specifications	Status	A / E*	Appln level	Applicable section of the Act
QSX	Range—more restrictive	O			
QSE	Range—less restrictive	A	-	C2	9D(3)
QST	Addition of an extra test	O			
QSU	Deletion of an existing test	A	-	C2	9D(3)
QSA	Analytical method—to comply with amendments to a standard (i.e. the BP, EP, USP or a Therapeutic Goods Order)	O			
QSB	Analytical method—which has been demonstrated to maintain or improve analytical performance (accuracy, precision and/or specificity)	O			
QSC	Analytical method—other than as specified above in change QSB	A	-	C2	9D(3)
QSM	Manufacturer of starting material (specifications unchanged)	O			
QSS	Supplier of starting material	O			

Packaging changes

Change codes	Packaging changes	Status	A / L*	Appln 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 is of a type listed in assurance 15	SAR	5, 10, 13, 15 & 16	C1	9D(3)
KGL	Container material—clear to coloured glass	O			
KBL	Container material—if the container is a blister pack, the goods are a solid dosage form (e.g. tablet) and the change is of a type listed in assurance 18	SAR	5, 10, 13 & 18	C1	9D(3)
KOT	Container material—other than in changes KBT, KGL or KBL	A	-	C2	9D(3)
KCL	Closure	SAR	5, 13	C1	9D(3)
KSL	Tamper evident seal—addition (including label notice to alert consumers to presence of seal)	O			
KSX	Tamper evident seal—removal (including removal of label notice re seal)	O			

Change codes	Packaging changes	Status	A/D*	Appln level	Applicable section of the Act
KWA	Inert wadding material—addition, substitution or removal where stability is not affected by the action	O			
KDA	Desiccant—inclusion in container	A	-	C2	9D(3)
KDX	Desiccant—removal from container	A	-	C2	9D(3)
KPP	Specifications of primary pack (other than labelling)	O			
KSP	Introduction of a measuring device (e.g. spoon, cylinder) or applicator (e.g. finger cot); this change can include graphical representation of the device on the label (copy of current & proposed label must be supplied if label is changed)	SAR	5	C1	9D(3)
KMD	Changes to existing measuring device (e.g. spoon, cylinder) or applicator supplied with the goods or removal of a measuring device or applicator, where other means of accurately measuring or applying the dose are readily available	SAR	5	C1	9D(3)
KPA	Introduction of a primary pack (no new text or graphics)	SAR	5, 14	C1	9D(3)
KPI	Introduction of a package insert where there is no requirement for supporting data	A	-	C2	9D(3)
KPD	Introduction of a package insert where supporting data or a justification for not providing supporting data is required	A		C3	9D(3)

Change codes	Packaging changes	Status	A/D*	Appln level	Applicable section of the Act
KRI	Removal of a package insert where there is no requirement for supporting data	A	-	C2	9D(3)
KRD	Removal of a package insert where supporting data or a justification for not providing supporting data is required	A		C3	9D(3)
KPX	Removal of a primary pack	SAR	5, 17	C1	9D(3)
KRP	Introduction of a refill pack	A	-	C2	9D(3)
KRR	Removal of refill pack	SAR	-	C1	9D(3)
MDA	Changes in pump or pump components of meter-dose aerosol (e.g. valve material)	A		C2	9D(3)

Manufacturing changes—finished product

Change codes	Manufacturing changes—finished product	Status	A / L*	Appln level	Applicable section of the Act
MMA	Addition or deletion of TGA licensed Australian manufacturer (includes site of manufacture)	SAR	5, 9	C1	9D(3)
AMS	Addition or deletion of steps of manufacture of a TGA licensed Australian manufacturer	SAR	5, 9	C1	9D(3)
MOS	Addition or deletion of an overseas manufacturer (includes site of manufacture	SAR	5, 9	C1	9D(3)
OMS	Addition or deletion of steps of manufacture of an overseas manufacturer	SAR	5, 9	C1	9D(3)
MPR	Manufacturing process (other than MBS)	SAR	13	C1	9D(3)
MBS	Batch size for pressurised inhalation (nasal and oral respiratory) products	A	-	C2	9D(3)
MUP	GMP clearance NUMBER update. Note: no other change to record permitted under this code. If amending steps of manufacture use change code OMS	SAR (fee exempt)	5	C1	9D(3)
MST	Change to manufacturing site and/or process of sterile product	A		C2	9D(3)

Consumer Medicine Information (CMI)

Change codes	Consumer Medicine Information (CMI)	Status	A / L*	Appln 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 'Label 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			

Product Information (PI)

Change codes	Product Information (PI)	Status	A / L*	Appln level	Applicable section of the Act
DPI	Introduction of a PI for an existing product where there is no requirement for supporting data	A	-	C2	9D(3)
DPD	Introduction of a PI for an existing product where supporting data or a justification for not providing supporting data is required	A		C3	9D(3)
DRS	Addition of more restrictive safety-related statements	SRR	5, PI	C1	9D(2)
DOT	Changes other than the addition of more restrictive safety-related statements where there is no requirement for supporting data	A	-	C2	9D(3)
DOD	Changes other than the addition of more restrictive safety-related statements where supporting data or a justification for not providing supporting data is required	A	-	C3	9D(3)

Other

Change codes	Other	Status	A/D*	Appln level	Applicable section of the Act
CTA	Correction of ARTG record in accordance with section 9D(1) of the *Therapeutic Goods Act 1989*	SAR	E, 5, 21	C1	9D(1)
BED	Brand equivalence statement intended for PBS listing where supporting data or a justification for not providing supporting data is required	A		C3	
BES	Brand equivalence statement intended for PBS listing where there is no requirement for supporting data	A		C2	
OTH	Other changes: an application using this code must include written advice from the TGA advising the application level for the change	Ask			

*A/D = assurances to be given and supporting documentation required for the given status to apply. Refer to Changes Table codes for an explanation of all codes used

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