Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

C1 application checklist for over-the-counter (OTC) medicines

Use this checklist to produce a high quality C1 application. You do not need to submit this checklist.

This checklist assists sponsors to prepare a change application at the C1 level for a registered OTC medicine. It is intended as an educational and self-check tool for sponsors. You do **not** need to submit this checklist with your application.

Preparing your applications in accordance with this checklist and the relevant guidance will assist you to:

- produce high quality C1applications
- submit applications at the correct level
- minimise the time required for the TGA's assessment.

About C1 applications

Most changes to an OTC medicine registered in the Australian Register of Therapeutic Goods (ARTG) require TGA approval prior to the change being made. Applications to change an OTC medicine are categorised into four levels (C1-C4) according to risk.

C1 changes are classified as 'negligible risk' to the quality and non-quality aspects of the medicine. These changes do not require assessment of safety, efficacy or quality data, or a justification for not providing such data. It is therefore intended that these applications can be processed in a short timeframe with minimal assessment.

Significant prolongation of evaluation timeframes for C1 applications (which has a flow-on effect to other applications) occurs when:

- an application is submitted at the incorrect level
- the application only includes the main change and does not include all changes being made to the medicine (including consequential changes)

This checklist is intended to reduce the occurrence of incomplete C1 applications and submissions at the incorrect level.

Relevant guidance on changing an OTC medicine

Consider this checklist in conjunction with the following guidance:

- Process to change a registered OTC medicine
- Changing an OTC medicine in the Australian Register of Therapeutic Goods
- OTC application categorisation framework

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Reference D25-5276052

Guidance on making change applications	Check
I have read and referred to the guidance documents listed above prior to preparing and submitting any change applications for registered OTC medicines.	☐ Yes

Note
Where a change application includes multiple changes covering different categories, the whole application is to be classified at the level of the highest category change in the application.

Guidance that applies to all change applications

Cover letter

Cover letter considerations	Check
I have read the guidance on Preparing an OTC application cover letter and considered the relevant points listed under Cover letter basics and Applications to change a medicine when writing my cover letter.	☐ Yes
The application cover letter outlines the nature and scope of the application and provides relevant and appropriate background, including the reasons for the requested change. **Note** Simply listing the change codes in the cover letter is **not** sufficient.	☐ Yes
Where multiple changes are proposed, the proposed changes are presented in a table with suitable headings (e.g. current registration details, proposed registration details, reason for change, reference to supporting documents, change code, application level)	☐ Yes
The cover letter is on company letterhead and signed by a person or agent authorised to conduct business on behalf of the applicant.	☐ Yes
I have checked that all the relevant documentation and supporting information referred to in the cover letter are included in the dossier.	☐ Yes
I have checked that the information in the cover letter is consistent with the information in the electronic application form in the TGA Business Services (TBS) portal.	☐ Yes

Selection of change codes

Change code considerations	Check
I have read the description of relevant change codes in the Changes Table and selected the most appropriate change code(s) for the proposed change(s) **Tip** There may be more than one change code in the Changes Table for a particular type of change. For example, there are more than 3 possible change codes for changes to the manufacturing process for a finished product. Carefully read through the descriptions of **all** the relevant change codes to identify the most appropriate change code that applies to your product and your proposed change.	☐ Yes

I have identified any consequential or additional changes in addition to the primary or main change proposed. **Tip** Some changes have consequential effects. For example, removal of a printing ink from the formulation of a hard capsule will result in change to the visual identification of the dosage form, the description in the finished product specification and in the Product Information document.	☐ Yes
I have checked that each proposed change is covered by a change code. **Note** It is important that you select the correct change codes as these will determine the application level. If you are applying to make more than one change, the change code with the highest application level determines the overall application level. For example, if you lodge an application to change the sponsor logo (change code LSP, application level CN) and reformat pre-existing text (change code LFO, application level C1) on the labelling, the overall application level will be C1.	☐ Yes
When submitting an application at the C1 level application, I have checked to ensure that all the changes, including consequential changes, fall within the scope of a C1 level application.	☐ Yes

Assurances required for each change code

Assurance considerations	Check
I have checked the required assurances for each change code selected.	☐ Yes
I am able to truthfully provide all the required assurances for the selected change code(s) at the time of submission. **Tip** Assurance 13 requires that the changeover **has been** validated. As such, any alternative assurances or declarations stating that the changeover **will be** validated are **not** acceptable for a change application. If you are unable to provide the required assurance at the time of submission, do not submit your application. You need to wait until you are able to truthfully provide the required assurance.	☐ Yes

Electronic application form

Application form considerations	Check
I have included all the relevant change code(s) in the application form.	☐ Yes
I have edited relevant fields in the electronic application form and product record at the time of submission to reflect the changes proposed in the application (e.g. relevant fields changed for product details such as pack size & poison schedule, manufacturer details, formulation details, visual identification)	☐ Yes
I have checked that information included in the application form (e.g. change codes, updated product details) are consistent with the proposed changes described in the cover letter.	☐ Yes

Dossier

Dossier considerations	Check
The dossier has been compiled in accordance with Parts A to D of the General dossier requirements	☐ Yes
The organisation and structure of the dossier is in Common Technical Document (CTD) format. **Note** While CTD format is mandatory, it is optional for the dossier to be in electronic Common Technical Document (eCTD) or Non eCTD electronic Submission (NeeS) format (i.e. with an e-identifier and sequence number). If the initial registration application was submitted in eCTD (or NeeS) format, then subsequent change applications should continue to be in eCTD (or NeeS) format.	☐ Yes
Module 1 of the dossier has been prepared in accordance with CTD Module 1: OTC medicines.	☐ Yes
The dossier contains all the necessary documentation required for the application level and to support the proposed change(s).	☐ Yes

Advice on particular types of change

Labelling changes

A product's label (as defined in the *Therapeutic Goods Act 1989*) includes the label attached to the container (e.g. bottle, tube or blister pack), the primary pack (e.g. carton) and any printed information supplied with the container or primary pack (e.g. package insert).

Labelling considerations	Check
I have provided the following documents in Module 1.3.3: ☐ Currently approved label ☐ Annotated label highlighting the differences between the current and proposed label ☐ Proposed label	☐ Yes
I have selected the relevant change code(s) to capture all the proposed labelling changes.	☐ Yes
Where multiple changes are proposed, I have included a summary table listing all the changes proposed.	☐ Yes
I have stated in the cover letter which label the change applies to (e.g. carton, bottle, blister foil or tube).	☐ Yes
I have stated in the cover letter which pack sizes the change applies to. **Note** Where the only difference in labelling between pack sizes is the quantity, only one set of labels need to be submitted, provided that an assurance to that effect is supplied with the application. Where there are a range of pack sizes approved with different poison schedules, submit a representative sample of labels from each poison schedule.	☐ Yes
Where changes to the font size or text height on the labels are proposed, I have checked that the proposed labels remain compliant with relevant labelling requirements (e.g. TGO 92, Poisons Standard)	☐ Yes

Product Information (PI)

PI considerations	Check
I have provided the following documents in Module 1.3.1: ☐ Currently approved PI document ☐ Annotated PI (marked up version) ☐ All additions, deletions and changes to the document are identified using 'track changes' ☐ Justification for the differences between the current and proposed PI are included as comments within the tracked changed document (or in a table in the cover letter) ☐ Proposed PI – clean copy	☐ Yes
I have selected the relevant change code(s) to capture all the proposed changes to the PI. **Tip** Where an approved PI document is to be reformatted to the new PI format, the relevant change code is DRF.	☐ Yes

Package inserts

Package inserts are treated as part of the labelling.

Package insert considerations	Check
I have selected the relevant change codes for Labelling (including package insert) changes to capture the proposed changes to the package insert. **Tip** Where a Consumer Medicine Information (CMI) document is supplied as a package insert and you intend to update the currently approved CMI (package insert) to the improved CMI template, this entails deletion, addition and rewording of text and is beyond the scope of a C1 level application.	☐ Yes
I have provided the following documents in Module 1.3.1: ☐ Currently approved package insert ☐ Annotated package insert (marked-up version) ☐ Proposed package insert – clean copy	☐ Yes

Manufacturing process

Manufacturing process changes for a finished product include changes to the manufacturing process and in-process controls as well as changes to the batch size.

Manufacturing process considerations	Check
I have checked whether the product is a sterile product. **Tip** For sterile products the possible change codes include MSS or MST.	☐ Yes

I have checked whether the product is considered a 'higher risk' OTC product which includes: • 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). **Tip** For 'higher risk' OTC products the possible change codes include MPH or MPD. The description for change code MPH mentions that the changes **have been demonstrated**, for the product, to be equivalent to or superior to the approved manufacturing process. If your proposed change does not fit the description of change code MPH, then you will need to use the higher-level change code MPD.	☐ Yes
I have carefully read through the descriptions of all the relevant change codes to identify the most appropriate change code that applies to the particular product. **Tip** Assurance There are more than 3 possible change codes in the Changes Table for changes to the manufacturing process for a finished product.	☐ Yes
I am able to truthfully provide all the required assurances for the selected change code at the time of submission. **Tip** Assurance 13 requires that the changeover **has been** validated. As such, any alternative assurances or declarations stating that the changeover **will be** validated are **not** acceptable for a change application. If you are unable to provide the required assurance at the time of submission, do not submit your application. You need to wait until you are able to truthfully provide the required assurance.	☐ Yes
I have outlined in the cover letter the nature of the proposed changes and provided relevant and appropriate background including the reasons for the requested changes.	☐ Yes
I have included a summary table comparing the currently approved vs proposed manufacturing process.	☐ Yes

Correction of ARTG record

Correction of ARTG record	Check
The proposed correction of ARTG record is in accordance with section 9D(1) of the *Therapeutic Goods Act 1989* whereby the information currently in the ARTG entry is incomplete or incorrect and the requested variation would complete or correct the entry.	☐ Yes
The error occurred at the time of initial registration or at some point during the regulatory lifecycle of the product.	☐ Yes

Evidence to support the proposed correction has been included with the application. EXAMPLE 1: The product was 'grandfathered' and the formulation details entered in the ARTG are incomplete (e.g. missing the quantities of some excipients) or incorrect and do not fully reflect the formulation when the product was first entered in the ARTG. Supporting evidence may include historical documentation, such as batch records showing the complete formulation details when the product was first entered in the ARTG. EXAMPLE 2: The shelf-life details are incorrectly stated in the ARTG and do not reflect the currently approved shelf-life. If an extension of shelf-life was recently approved but the new shelf-life is not correctly reflected in the ARTG, then a copy of the approval letter for the shelf-life extension should be provided as evidence.	☐ Yes

OT1 change code

The OT1 change code is for 'Other' changes – application level C1. An 'other' code is used only when no other code applies and written advice from the TGA is required authorising the use of the code.

OT1 change code considerations	Check
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 included with the application.	☐ Yes

Simultaneous applications for the same medicine

If possible, avoid submitting an application to make changes to a medicine while another application to change the same medicine is in progress. When more than one application for the same medicine is in progress simultaneously, the approved change(s) to the ARTG details may be overwritten when the subsequent application is finalised.

Simultaneous applications	Check
If simultaneous change applications cannot be avoided and need to be submitted for a particular medicine, I have notified the TGA in the cover letter of the submission ID numbers for the application(s) already in progress for the same medicine.	☐ Yes

Changing more than one medicine

If you want to change more than one medicine you will **usually** need to submit a separate application for each medicine that you want to change.

Changing more than one medicine	Check
You can submit a single application to make identical changes to more than one OTC medicine only when **all** of the following apply: ☐ The change codes correspond only to applications made under section 9D of the Act. ☐ The specific details of each of the changes are identical and common to each medicine in the application. ☐ The changes do not require separate evaluation in the context of each medicine. **Tip** Take into account both the currently registered details and the proposed details for each medicine when you assess whether the change is identical. If one or more of the medicine applications includes a unique change you will need to submit separate applications. EXAMPLE: If you propose addition of the same manufacturer to 4 medicines and changes to the font size on the label for only one of the 4 medicines, you cannot submit a single application but will need to submit two applications as follows: 1. one application to add the manufacturer to 3 of the medicines, as this is an identical change to all 3 medicines 2. a second separate application to add the manufacturer and make the changes to the label of the fourth medicine.	☐ Yes

Safety-related requests

Safety-related requests include the addition of **more restrictive** safety-related statements to the labels, PI and CMI.

Safety-related requests	Check
In accordance with section 9D(2) of the *Therapeutic Goods Act 1989*, the proposed changes either adds a warning or precaution OR reduces the class of persons for whom the goods are suitable. EXAMPLE 1: Changing a warning statement from 'Check with your doctor before use if you have liver disease' to 'Do not use if you have liver disease'. The proposed warning statement is considered a more restrictive safety-related statement as the warning is changing from a precaution to a contraindication. EXAMPLE 2: Addition of a new warning or precaution including a new RASML statement. EXAMPLE 3: Changing the currently approved patient population from 'Adults and children 6 years and over' to 'Adults and children 12 years and over'. This is considered a reduction in the class of persons for whom the goods are suitable.	☐ Yes
I have updated all the relevant documents (e.g. labels, PI & CMI) where applicable.	☐ Yes