Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

International harmonisation of ingredient names (IHIN) – Dual labelling transition to sole medicine ingredient names

Consultation paper

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Purpose

The Therapeutic Goods Administration (TGA) is seeking views on medicine ingredient names that must be displayed as both the old and new ingredient name ('dual labelled') on labels and Product Information (PI) and Consumer Medicine Information (CMI) documents until 30 April 2023 as part of International harmonisation of ingredient names (IHIN).

We want to know if health care professionals, consumers, health care systems and clinical software providers are ready to start seeing all dual labelled ingredient names as sole ingredient names on medicine labels and in PI/CMI documents after 30 April 2023. Alternatively, we want to know if you think more time is needed for any specific ingredient names that are currently required to be dual labelled.

We are also seeking feedback on a proposal for the transition of dual labelled names to sole ingredient names. We want to know if you think a process is required to transition medicine labels and PI/CMI documents in a specific time frame, to give clarity to health professionals, consumers and medicine sponsors and ensure timely changes occur across all products containing specific ingredients.

Have your say

We are seeking your views on:

- whether you think health professionals, consumers and health systems are ready for dual labelling to end for all dual labelled ingredient names (Part 1)
- a proposal to transition medicine labels and PI/CMI documents to sole medicine ingredient names in a specific time frame (for names suitable for transition) (Part 2).

Your feedback will help to inform the approach to how the 36 dual labelled medicine ingredient names will need to appear on labels and PI/CMI documents of medicines released for supply from 1 May 2023.

We invite you to give your feedback by completing our online survey on the TGA Consultation Hub to answer the questions in this consultation paper. We will publish responses on the TGA Consultation Hub, unless you request that your response be kept confidential.

Depending on the feedback received on this consultation, we may also seek further feedback from respondents on the implementation options of a transition plan. If you are happy to be contacted, please let us know in the online survey.

If you have any questions about this consultation, please contact TGA.Scientific@health.gov.au.

Background

International harmonisation of ingredient names (IHIN)

In 2016, the TGA updated some medicine ingredient names used in Australia to align with names used internationally. This was done to reduce confusion for Australian consumers and healthcare professionals who travel internationally, health professionals who have trained overseas or people trying to access medicine information online.

Harmonisation of ingredient names has also been done by some other countries over the years, including the United Kingdom in 2003 and New Zealand in 2008.

Medicine companies were given four years to update medicine labels and PI and CMI documents with the new ingredient names. This transition period ended on 30 April 2020. All affected medicines released for supply from 1 May 2020 are required to reflect the updated ingredient names on labels and in supporting documents such as PI and CMI leaflets.

Dual labelling until 30 April 2023

Certain ingredient name changes were identified as being of higher clinical significance, for example the change from benzhexol to trihexyphenidyl. For these types of changes, medicine labels were required to display the old and new ingredient name from 1 May 2020 until 30 April 2023, to help consumers and health professionals become familiar with the new name. These ingredient names requiring 'dual labelling' must be displayed in the format 'new ingredient name (old ingredient name)'. For example, medicines containing trihexyphenidyl need to be dual labelled as 'trihexyphenidyl (benzhexol)'.

PI and CMI documents for medicines requiring dual labelling must make reference to both the old and new ingredient name but the old name does not need to be repeated throughout the document.

The list of updated medicine ingredient names was published on the TGA website with ingredients required to display both the old and new ingredient name included under the heading 'Dual labelling.' A list of ingredients requiring dual labelling is included in Appendix A (see both Table 1 and Table 2).

Adrenaline (epinephrine) and noradrenaline (norepinephrine)

Adrenaline (epinephrine) and noradrenaline (norepinephrine) are not included in the list of 'dual labelled' ingredient names.

When TGA updated some medicine ingredient names, adrenaline and noradrenaline remained as the approved names in Australia, but medicines containing these ingredients were required to start also including the international names epinephrine and norepinephrine on labels and information leaflets. There is no intent to move to using only epinephrine and norepinephrine as the new ingredient names.

When dual labelling ends on 30 April 2023, there will be no changes to how 'adrenaline (epinephrine)' and 'noradrenaline (norepinephrine)' and their related salts will be displayed on medicine labels and PI/CMI documents.

Active ingredients and trade names

Ingredients requiring dual labelling are active ingredients. An active ingredient is the substance in a medicine with a therapeutic effect (the substance in a medicine that makes it work).

Some medicines use the active ingredient name as part of the product's trade name (sometimes known as the product name, proprietary name or 'brand name'). IHIN involved updating names of ingredients contained in medicines, not the trade names of medicines. The TGA did not require trade names to be updated but medicine sponsors may have voluntarily updated trade names to avoid confusion.

Australian approved ingredient names

The TGA develops and maintains approved terminology, including approved names for ingredients in medicines, to ensure the accuracy and consistency of information on the Australian Register of Therapeutic Goods (ARTG). Consistency in naming helps people retrieve information from the ARTG, avoids the risk of confusion between goods and facilitates interoperability with other health related tools such as eHealth and the Pharmaceutical Benefits Scheme (PBS).

Approved ingredient names are included in the Ingredients Table to form the 'Australian Approved Names List for Therapeutic Substances' which is publicly accessible and searchable through the TGA eBS website.

Legislative basis for using dual labelled ingredient names on medicine labels and PI/CMI documents

Approved names of active ingredients must be included on medicine labels as specified in Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines (TGO 91) and Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines (TGO 92). Section 6 of TGO 91 and TGO 92 defines 'name of an active ingredient' as 'the name of the active ingredient that is accepted for inclusion in the Australian Approved Names List.' 'Australian Approved Names List' is defined in the Therapeutic Goods Regulations 1990 ('the Regulations').

Ingredient names requiring dual labelling are in the Australian Approved Names List in the format 'new ingredient name (old ingredient name) salt hydrate', for example lidocaine (lignocaine) hydrochloride monohydrate.

To allow for the length of dual ingredient names, TGO 91 and TGO 92 permit active ingredients in Schedule 2 (dual labelled ingredients) to be included on the main label of medicines in a smaller minimum text size (2.5 mm) for certain sized containers until 30 April 2023.

The *Therapeutic Goods Act 1989* outlines requirements for PI documents including that a form can be approved in 7(D). The form for providing product information requires the 'Australian Approved Name' for the name of the medicine (active ingredients). The Regulations outlines requirements for CMI documents including that they must be consistent with the PI and set out in the CMI template.

Active ingredient awareness

The Australian government has implemented initiatives to encourage general awareness around active ingredients in recent years to support safe and appropriate use of medicines.

In 2016, the TGA introduced new medicine labelling rules to make important information about medicines easier to find. Under these rules, active ingredients need to be more prominent and should be easily found below or next to the product name on the front of the medicine pack.

Since February 2021, prescriptions for Pharmaceutical Benefits Scheme (PBS) and Repatriation PBS medicines must show their active ingredients. If a doctor wants to include the brand name, it will appear after the active ingredient name. Active ingredient prescribing was introduced to help people understand what medicines they are taking.

These recent initiatives are an important factor in considering if stakeholders are ready for dual labelling to end. Assisting health professionals and consumers to better identify the active ingredient name may mean sole ingredient names are more noticed than expected when dual labelling began.

Part 1: Are you ready for all dual labelled medicine ingredient names to transition to sole names?

The medicine ingredient names required to be displayed on medicine labels and PI/CMI documents as both the old and new name (dual labelled) are included in Appendix A. The list is split into two tables. Table 1 is a list of ingredient names we propose to update to the intended sole ingredient name when the dual labelling period ends. Table 2 is a list of ingredient names we are especially seeking your feedback on before we update them to intended sole names. We want to know if you think any of the ingredients in Table 2 should be dual labelled for a longer time for safety, familiarity or other reasons.

These lists include how both names need to be currently displayed, for example trihexyphenidyl (benzhexol) hydrochloride, and how the ingredient names are planned to start to appear after the dual labelling periods ends and sponsors update labels and PI/CMI documents to remove the old ingredient name. (The original plan for end of dual labelling is explored further in Part 2 of this consultation paper).

Most dual labelled medicine ingredients are in prescription medicines, meaning health professionals are involved in prescribing and supplying these medicines, however some ingredients such as lidocaine (lignocaine) are found in multiple types of medicines including those that may be self-selected and purchased by consumers over-the-counter.

Familiarity with new ingredient names

The three-year time frame for requiring dual labelled ingredient names was an estimation of how long it would take health professionals and consumers to become familiar with the new ingredient names. This time frame could not have predicted the impact of a pandemic on the health systems and medicine supply chains.

To support the transition to new ingredient names for health professionals and consumers, dual labelled ingredient names include the new ingredient name first, followed by the old name in brackets.

We are now seeking feedback as part of this consultation on familiarity with the new names. We want to make sure that the use of sole ingredient names would not cause any confusion or potential medication errors, particularly given active ingredient awareness initiatives.

Three years may be sufficient time to become familiar with new ingredient names, but there are other risks with removing the old name on medicine labels that also need to be considered. This is explored further in implications and considerations for the end of dual labelling.

Part 1 Questions

1. Are health professionals familiar with the proposed sole ingredient names listed in Appendix A (both Table 1 and Table 2)? If not, please tell us which names you think may still be unfamiliar to health professionals.
2. Do you think consumers who are currently using affected medicines are familiar with the new ingredient names?

Implications and considerations for the end of dual labelling

Changes on medicine labels and in electronic systems

Changes to medicine labels take time and appear gradually as new stock is distributed, and existing stock is sold, to support the medicine's availability in the community.

From May 2023, we expect that labels, PIs, CMIs and other documents will gradually be updated to use the sole ingredient names in Appendix A. Medicine sponsors might also change the brand names of these medicines to reflect the sole ingredient name. Under the original plan for the end of dual labelling, these updates were to be voluntary, which is likely to draw-out the process with no defined end date (this issue is explored further in Part 2 of this consultation paper).

Changes to medicine labels and PI and CMI documents may occur at different times to changes in electronic health care systems (for example, prescribing and pharmacy dispensing software systems). This means the name on a prescription or a dispensing label, may be different to the ingredient name on the medicine label at some point during the transition.

Consumers and health care professionals will need to be aware of these changes to avoid confusion and ensure the correct medicine is prescribed and taken. The TGA plans to work with stakeholders on communicating these changes to health professionals and consumers.

Types of changes and searchability in systems

Some of the new sole ingredient names bear no resemblance to the old ingredient name (for example, 'benzhexol' vs 'trihexyphenidyl'). The level of similarity between the old and new names may impact searchability in electronic systems when dual labelling ends. As part of this consultation, we are seeking feedback from software vendors and health care professionals about the impact on searching for ingredient names when dual labelling ends.

Similarity between ingredient names mercaptamine (cysteamine) and mercaptopurine

The TGA is aware of the similarity between ingredient names mercaptamine (cysteamine) and mercaptopurine.

The removal of the old name on mercaptamine medicines when dual labelling ends may make the ingredient names mercaptamine and mercaptopurine appear more similar. There is a risk of severe consequences if these medicines are mistaken for each other. While clinical risk management strategies may address this similarity, we want to hear from health professionals if you think the dual labelling requirements for mercaptamine can end in April 2023 or if it should continue to be dual labelled as 'mercaptamine (cysteamine)' for longer.

As part of this consultation, we also want to hear if there are any safety concerns about the removal of the old ingredient name for any of the other dual labelled ingredient names, especially those listed in Table 2.

Ingredient names not used in medicines included in the ARTG

Some of the ingredient names in the dual labelling list (Appendix A) are not currently being used in medicines included in the ARTG. This means that health professionals and consumers may not have had the same opportunity to become familiar with these new ingredient names than for other dual labelled ingredient names. For example, there are no current products on the ARTG containing asparaginase (colaspase) or estropipate (piperazine oestrone sulfate).

Some medicines using dual labelled ingredient names are not included in the ARTG but may be accessed in other ways such as through the Special Access Scheme (SAS). Medicines accessed under the SAS are exempt from TGO 91 and TGO 92 and therefore are not required to include the approved name on medicine labels, including affected ingredient names in the dual labelling format.

We propose to update dual labelled ingredient names not currently used in medicines included in the ARTG to sole names after 30 April 2023. However, we want to know if there is a justification to keep any of the following ingredient names in the dual labelled format in the Ingredients Table for longer for historical or clarity purposes:

- asparaginase (colaspase)
- estropipate (piperazine oestrone sulfate)
- alimemazine (trimeprazine) tartrate.

If these names are not updated to sole names, it would mean that if a medicine containing these ingredients was entered in the ARTG in the future, the medicine label and associated documents would need to display the active ingredient in the dual labelling format (unless the approved name changed in the meantime).

Should the dual labelling period be extended for some ingredient names?

The TGA is proposing to update all the dual labelled ingredient names to sole names listed in Appendix A (Table 1 and Table 2) after 30 April 2023 to support the goal of international harmonisation of ingredient names. We want to know if you think there are reasons why any

of the ingredient names should be dual labelled for a longer period, especially those ingredients included in Table 2.

Text size allowances for dual labelled ingredient names on medicine labels ending 30 April 2023

TGO 91 and TGO 92 specify reduced text size requirements for IHIN dual labelled active ingredient names on the main label of certain size containers to allow for longer names until the end of April 2023.

We are seeking feedback on if you think the text size requirements of TGO 91 and TGO 92 from 1 May 2023 are suitable if the dual labelling period is extended for some ingredients or if you think the text size allowances for dual labelled ingredient names would need to continue.

Part 1 Questions continued

3. Do you agree that all the ingredient names in Table 1 can be updated to sole names at the end of the dual labelling period? If not, please tell us which ingredients you think need to be dual labelled for longer, why, and how long you think they need to remain dual labelled.
4. Do you think mercaptamine should continue to be dual labelled as mercaptamine (cysteamine) for a longer period? Why? If yes, for how long?
5. Do you think the following ingredient names (not currently being used in medicines included in the ARTG) should remain in the dual labelling format in the Ingredients Table for historical and clarity purposes or other reasons? Why? If yes, please tell us which ingredients and how long you think they need to remain in the dual labelling format.

   a. asparaginase (colaspase)
   b. estropipate (piperazine oestrone sulfate)
   c. alimemazine (trimeprazine) tartrate.

6. Do you think the three-year dual labelling period due to finish on 30 April 2023 should be extended for any other ingredient names in Table 2 not already mentioned in question 4 and 5? Why? If yes, please tell us which ingredient names, and for how long.
7. Please tell us about the impacts if the dual labelling period was extended for any ingredient names. If you are a medicine sponsor, please also tell us the estimated costs of these impacts.
8. If the dual labelling period was extended for some ingredients, do you think the main label text size allowances in TGO 91 and TGO 92 would also need to be extended for those ingredients? Why?
9. Please tell us about any challenges with searching in software systems using old ingredient names that we should consider, particularly if you are or represent software vendors or are a health professional.
10. Please tell us if you have any further comments or information about implications and considerations for the end of dual labelling.

Part 2: Transition from dual labelling to sole ingredient names

Part 2 of this paper explores a proposal for the transition from dual labelled ingredient names to sole names at the of the dual labelling period (for those names considered suitable to transition).

Original plan for end of dual labelling

Medicine sponsors must display the old and new ingredient names until 30 April 2023. After that date, the original plan was for medicine sponsors to voluntarily update labels and PI/CMI documents to remove the old ingredient name. The TGA was going to notify affected sponsors when the dual-labelling period ended.

At the end of the dual labelling period, the TGA was planning to change the dual labelled ingredient names to sole names in the Ingredients Table by updating each dual labelled entry. TGA would include in each entry the previously used dual labelled name as a synonym for the new ingredient name. Therefore, searches of the Ingredients Table using an old name will retrieve the new sole name entry.

These Ingredients Table changes would flow through to affected ARTG entries and be visible in the public ARTG.

We expected that most medicine sponsors would support moving to sole ingredient names on medicine labels over time under this original plan. However, it would be difficult to give clarity and certainty to consumers and health professionals about when changes are expected, so we are seeking your feedback on a proposal to move away from the original plan and implement a transition period.

As well as risk of uncertainty, there are labelling requirements in TGO 91 and TGO 92 that do not allow or support the original plan to be implemented. These issues are further discussed below and support the proposal to shift to an alternative transition plan.

Labelling requirements and the original plan for the end of dual labelling

Cohesive unit labelling requirements for medicines

The current cohesive unit labelling requirements do not support the original plan for voluntary updates to medicine labels. Subsection 9(3) of TGO 91 and TGO 92 requires that the name of the medicine, active ingredient and quantity of active ingredients appear as a cohesive unit on the main label without interruption of additional information, except in certain circumstances. This means that continuing to include the old name in the dual label format in the cohesive unit on medicine labels after 30 April 2023 would not be compliant with labelling requirements.

Main label text size allowances for dual labelled ingredient names on medicine labels ending 30 April 2023

Medicine sponsors who do not voluntarily update their medicine labels to reflect the sole ingredient name will also need to consider if they meet the general text size requirements specified in TGO 91 and TGO 92 from 1 May 2023 when the main label text size allowances for dual labelled ingredients ends (as set out in Section 9 and Schedule 2).

New proposed transition period from dual labelling to sole ingredient names

The aspect of the original plan for medicine sponsors to voluntarily change labels and PI/CMI documents to remove the old ingredient name has the risk of being a drawn-out and inconsistent process. It could mean, for example, in ten years, there may be different products with the same active ingredient still expressing the active ingredient differently.

Therefore, the TGA is proposing to transition labels in a certain time frame, to ensure consistent and timely changes occur across all products containing specific ingredients. Implementing a transition period would help to support communication activities providing clarity to consumers, health professionals, software vendors and medicine sponsors.

We are seeking feedback on the impacts of implementing a transition period and suitable time frames for requiring labels and PI/CMI documents to be updated with the sole ingredient name (for those ingredient names considered suitable for transition).

Submitting requests to labels and PI/CMI documents during proposed transition period

Medicine sponsors would be required to submit updates to labels to reflect the updated sole name according to existing legislation and processes for the different medicine types during the proposed transition period.[1] Updates to PI/CMI documents should also be submitted according to existing legislation and processes.

For more information see:

- Variations to prescription medicines - excluding variations requiring the evaluation of clinical or bioequivalence data for variations to prescription medicines and biological medicines.
- Process to change a registered OTC medicine.

Part 2 Questions

11. Do you agree with the proposal to implement a transition period to require medicine labels to be updated with sole ingredient names within a certain timeframe? Why? Please tell us if you think a transition period would help in ensuring consistent and timely changes occur across all products containing specific ingredients, and would give more clarity for health professionals and consumers than the original plan?
12. Do you agree that PI/CMI documents of affected medicines should also be updated to reflect the sole ingredient name under a transition plan? Please tell us why and if you think that PI/CMI documents of other medicines that refer to the dual labelled ingredients should also be updated.

[1] Note under existing legislation and processes, some medicine types are not required to have PI/CMIs or submit updated labels to the TGA.

13. If a transition period was implemented, what do you think the transition time frame should be? Why?
    a. 1 year
    b. 2 years
    c. 3 years
    d. other.
14. Please tell us about the impacts if a transition period was implemented. If you are a medicine sponsor, please provide estimated costs of these impacts.
15. If a transition period was implemented, do you agree with the proposal for sponsors to request updates to labels and/or PI/CMI documents to reflect the updated sole name according to existing legislation and processes? Why?
16. Please tell us if you have any further comments about dual labelled medicine ingredient names.

Next steps

We will consider all feedback received before deciding on the approach to dual labelled ingredient names. We will inform stakeholders if there are any changes to the dual labelling period for any ingredient names or to the transition arrangements.

We will publish your response on the TGA Consultation Hub, unless you specifically request that your response be kept confidential.

If you have any questions about this consultation, please email TGA.Scientific@health.gov.au.

Appendix A: Medicine ingredient names requiring dual labelling until 30 April 2023

Medicine ingredient names currently required to be dual labelled have been split into two tables. Table 1 lists ingredient names proposed to update to sole names after 30 April 2023, and Table 2 lists ingredient names where we are seeking feedback on the timing of any update to sole names.

Table 1: Ingredient names the TGA proposes to update to sole names after 30 April 2023

The following table is a list of medicine ingredient names that we propose to transition to sole ingredient names at the end of the dual labelling period (after 30 April 2023).

Dual labelled medicine ingredient names we propose to transition to sole names

Group[2]	Proposed sole ingredient name	Current dual labelling required until 30 April 2023	Associated TGA ingredient IDs[3]
1	amobarbital amobarbital sodium	amobarbital (amylobarbitone) amobarbital (amylobarbitone) sodium	100607 52166
2	amphotericin B	amphotericin B (amphotericin)	96763
3	dactinomycin	dactinomycin (actinomycin D)	100600
4	calcitonin salmon calcitonin salmon acetate	calcitonin salmon (salcatonin) calcitonin salmon (salcatonin) acetate	100596 100597
5	doxycycline hyclate	doxycycline hyclate (hydrochloride)	56591
6	formoterol formoterol fumarate formoterol fumarate dihydrate	formoterol (eformoterol) formoterol (eformoterol) fumarate formoterol (eformoterol) fumarate dihydrate	96966 97220 97221
7	furosemide furosemide sodium	furosemide (frusemide) furosemide (frusemide) sodium	100588 102321

[2] There are 36 ingredient names in total in Table 1 and 2. Related names are grouped together in the tables.
[3] TGA ID number of current dual labelled approved name

8	glycopyrronium bromide	glycopyrronium bromide (glycopyrrolate)	108543
9	mecobalamin	mecobalamin (co-methylcobalamin)	93010
10	pentoxifylline	pentoxifylline (oxpentifylline)	100594
11	phenobarbital phenobarbital sodium	phenobarbital (phenobarbitone) phenobarbital (phenobarbitone) sodium	100696 100697
12	procaine benzylpenicillin	procaine benzylpenicillin (procaine penicillin)	100595
13	tetracosactide tetracosactide acetate tetracosactide zinc phosphate complex	tetracosactide (tetracosactrin) tetracosactide (tetracosactrin) acetate tetracosactide (tetracosactrin) zinc phosphate complex	100703 100704 100705

List of ingredients requiring dual labelling in the Australian Approved Names List the TGA intends to transition to sole names

Table 2: Ingredient names the TGA is seeking your feedback on before we update to intended sole names

The following table is a list of medicine ingredient names requiring dual labelling until 30 April 2023 that we also propose to update to sole names, but we are particularly seeking feedback on. We want to know if you think any of these ingredients should be dual labelled for a longer time for safety, familiarity or other reasons.

Dual labelled medicine ingredient names we are seeking feedback on

Group[4]	Proposed sole ingredient name	Current dual labelling required until 30 April 2023	Associated TGA ingredient ID[5]	Considerations
14	alimemazine tartrate	alimemazine (trimeprazine) tartrate	100598	Not currently being used in medicines included in the ARTG. The TGA is seeking feedback on if this name should remain dual labelled for a longer period for historical purposes, clarity or other reasons. Sole name is also significantly different to old name.
15	asparaginase	asparaginase (colaspase)	52966	Not currently being used in medicines included in the ARTG. The TGA is seeking feedback on if this name should remain dual labelled for a longer period for historical purposes.
16	dosulepin hydrochloride	dosulepin (dothiepin) hydrochloride	100587	Removal of old name when dual labelling ends may make the name appear more similar to another ingredient name 'doxepin.'
17	estropipate	estropipate (piperazine oestrone sulfate)	81933	Not currently being used in medicines included in the ARTG. The TGA is seeking feedback on if this name should remain dual labelled for a longer period for historical purposes.

[4] There are 36 ingredient names in total in Table 1 and 2. Related names are grouped together in these tables.
[5] TGA ID number of current dual labelled approved name.

18	hydroxycarbamide	hydroxycarbamide (hydroxyurea)	100662	Sole name is significantly different to old name. The TGA is seeking feedback on if there are reasons for this name to remain dual longer for a longer period.
19	lidocaine lidocaine hydrochloride lidocaine hydrochloride monohydrate	lidocaine (lignocaine) lidocaine (lignocaine) hydrochloride lidocaine (lignocaine) hydrochloride monohydrate	100665 100669 100666	Ingredient is used in multiple types of medicines.
20	mercaptamine mercaptamine bitartrate mercaptamine hydrochloride	mercaptamine (cysteamine) mercaptamine (cysteamine) bitartrate mercaptamine (cysteamine) hydrochloride	100634 100635 110286	Removal of the old ingredient name when dual labelling ends may make the ingredient names mercaptamine and mercaptopurine appear more similar. There is a risk of severe consequences if these medicines are mistaken for each other.
21	Mycobacterium bovis	Mycobacterium bovis (Bacillus Calmette and Guerin (BCG) strain)	96610	Sole name is significantly different to old name. The TGA is seeking feedback on if there are reasons for this name to remain dual longer for a longer period.
22	tetracaine tetracaine hydrochloride	tetracaine (amethocaine) tetracaine (amethocaine) hydrochloride	108088 100582	Sole name is significantly different to old name.
23	trihexyphenidyl hydrochloride	trihexyphenidyl (benzhexol) hydrochloride	52304	Sole name is significantly different to old name.

List of ingredients requiring dual labelling in the Australian Approved Names List the TGA is seeking feedback on

Version history

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