Australian Government
Department of Health
Therapeutic Goods Administration

Regulation impact statement

International Harmonisation of Ingredient Names

Version 1, November 2015

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 is responsible for regulating medicines and medical devices.
- The 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).
- 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 <https://www.tga.gov.au>.

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The problem

Ingredient names are a critical piece of information about medicines for doctors, nurses, pharmacists and patients. With a proliferation of trade names and generic medicines in the marketplace, ingredient names help doctors, nurses and pharmacists speak a common language. For patients, the ingredient name is increasingly what is used to inform their treatment regime and to access new supplies, particularly when travelling. Without consistency and surety around ingredient names, there is the risk of confusion about what treatment is being prescribed and medication error, potentially leading to serious risks and poor health outcomes.

Unfortunately, there is lack of consistency and global harmonisation for ingredient names. Aside from the confusion noted above, this also makes it difficult for health practitioners to identify emerging issues in the international medical literature and other communication channels. For example, an article appearing in an American journal about a problem with 'lidocaine' is about 'lignocaine' (in current Australian terminology).

Further, inconsistent naming in different countries creates an additional cost burden on industry stakeholders supplying in a global market. These costs extend further than just the costs of different labels for markets using different names – label requirements often differ across markets for other reasons (related to the public health decisions made by specific regulators). There is also an administrative cost involved in maintaining different sets of documents – dossiers, drug master files etc. – where the only difference is the ingredient name. Such additional costs to manufacturers and suppliers flow on to government health budgets and patients.

Objective

This Regulation Impact Statement (RIS) assesses options for the harmonisation of medicine ingredient names with international nomenclature systems, preferring the use of International Nonproprietary names (INNs) where possible. The INN system was developed by the World Health Organization (WHO) and is maintained by a committee of member states that includes Australia. The Therapeutic Goods Administration (TGA) proposes to update Australian ingredient names included in TGA's Business Services Ingredients Table to bring them into line with international nomenclature. Under this proposal, TGA will change a number of Australian ingredient names to their international name, with consequential effects on medicine records, labels and product information.

This will not resolve all of Australia's medicine ingredient name alignment issues. 'Paracetamol', for example, is the INN name already in use in Australia, while 'acetaminophen' is a United States Adopted Name (USAN); 'adrenaline', a name used in Australia is not the INN, which is 'epinephrine', but, as discussed herein, 'adrenaline' is so fixed in the Australian nomenclature that a change may create significant risk of medication error or risks associated with failure to administer medication (for example, an increase in prescribing and dispensing errors[1]). This harmonisation activity will, however, resolve many of the differences between the naming systems of Australia and other jurisdictions, while improving the current situation in a global marketing system.

[1] James, H. R. 'Ephedrine/epinephrine drug label confusion', Anaesthesia, 1998, Vol 53, issue 5. <http://onlinelibrary.wiley.com/doi/10.1046/j.1365-2044.1998.04771.x/pdf>

Options

This RIS outlines the anticipated impacts of the following options for ingredient name harmonisation:

Option 1: Status quo – No action.

Option 2: Mandatory adoption of harmonisation with international protocols - the full proposal – Adopt all the proposed name changes (478 ingredient names changed). The old ingredient names would be removed from the Ingredients Table and applicants would only be able to use the new ingredient names.

Option 3: Mandatory adoption - a reduced proposal – Reduce the full list of name changes, based on issues raised during consultation. This option removes ingredient name changes that have not been adopted consistently in the international market:

a. Maintain status quo for metal containing ingredients – No Latin-to-English name changes would be made to metal-containing ingredients.

b. Maintain status quo for sunscreen ingredients – No changes would be made to ingredients that are used as actives in current TGA-regulated sunscreens.

c. Maintain status quo for some excipient ingredients – No changes would be made to some excipients where the source reference did not apply this terminology.

d. Maintain status quo for macrogol excipient ingredients – No changes would be made to macrogol ingredients that are only used as excipients.

Under this option, 336 ingredient names would change.

Option 4: Mandatory adoption – only those changes based on direct harmonisation of INNs or references plus changes of high clinical significance – This option proposes to further reduce the full list by only implementing name changes where the replacement name has an international reference or an INN that does not require modification, plus a number specific ingredients identified as being of high clinical significance.

Under this option, 160 ingredient names would change.

Option 5: Voluntary name changes – New ingredient name entries would be included in the Ingredients Table and sponsors could voluntarily move to using the new names or continue to use the old ingredient name. Consequently, different products could use different ingredient names on their labels when they are actually referring to the same substance. This voluntary approach can be applied either to the full proposal or to a reduced list.

Two transition period options are presented for the mandatory adoption options (Options 2, 3 and 4):

- **Transition Option (i):** proposes a **three year** transition period for changing to the new ingredient names.
- **Transition Option (ii):** proposes a **four year** transition period for changing to the new ingredient names.

For both transition options, medicines with ingredients identified as of 'high clinical significance' would be dual-labelled with both the old and new name for an additional three years. Following this period, sponsors could then start using the new ingredient name as the sole name. Adrenaline and noradrenaline products were considered to be an exception to this rule. Both adrenaline and noradrenaline products would be dual-labelled indefinitely, consistent with the United Kingdom approach.

Option 3(ii) is the preferred option, with a transition period of four years. This option would better align Australian ingredient names with widely accepted international terminology, while not imposing harmonisation where the regulatory costs may outweigh the benefits. The four year transition period would minimise the costs associated with name changes as this fits with the business as usual label changes identified by industry stakeholders.

This proposal will result in an estimated cost to industry of **$0.13M** per annum over 10 years. This net regulatory cost will be offset by other qualitative gains, such reduced risk of incorrect use of medicines, improved access to international medicines information and clarity for patients and healthcare providers. This option will also result in a small reduction in barriers to trade for individual companies, however it is not expected to have a noticeable effect on the market overall.

Due to the qualitative gains from harmonisation, this option is expected to result in an overall net benefit to consumers, healthcare professionals and industry once the name changes are embedded in Australian nomenclature.

Consultation

In May 2013, TGA consulted on a proposal to change approximately 500 ingredient names. Thirty-one submissions were received from the therapeutic goods industry, and healthcare professional and consumer organisations. TGA also conducted focus groups with some stakeholders to discuss the proposed name changes and seek feedback on implementation strategies.

Consultation responses indicated broad in-principle support for international harmonisation of ingredient names. Healthcare professional and consumer organisations stated that harmonisation would reduce ambiguity and confusion by providing international consistency. With a few exceptions, most stakeholders agreed that the proposed changes would help the pharmaceutical industry provide Australians with medicine products, by making it easier to prepare labels and other documents for the Australian market. The exceptions were based on a perceived lack of international harmonisation with some of the proposed new names (for example, using INN terminology for sunscreen active ingredients).

Stakeholders also provided feedback on implementation, including valuable suggestions for communication and education strategies.

Implementation

During the transition period, industry and TGA will work together to update ingredient names in:

- The TGA Business Services Ingredients Table
- Formulation details within entries on the Australian Register of Therapeutic Goods (ARTG)
- Product Information and Consumer Medicine Information documents
- Medicine labels.

To minimise the effect of these changes on medicine sponsors, TGA will initiate amendments to affected ARTG entries. There is no fee associated with TGA initiated changes to ARTG entries, labels or supporting product documentation, as long as the only change made is to the ingredient name for the purposes of harmonisation.

TGA will also undertake a range of communication and education activities to minimise potential risks to consumer health and safety from ingredient name changes. TGA will work closely with consumer and healthcare professional organisations to develop and disseminate targeted

information about the ingredient name changes. These organisations have expertise in consumer matters and existing resources and networks that extend beyond those currently available to TGA.

Glossary of terms

Definitions of key terms used in this consultation paper are outlined in this section to help provide a common understanding of the key issues.

Active ingredient: the ingredient of the medicine that allows the medicine to have a therapeutic effect in the body.

Australian Approved Name (AAN): chemical substances that are used as ingredients in therapeutic goods are given Australian Approved Names (AANs).

Approved Biological Name (ABN): approved names for biological substances—that is, substances of biological origin (other than antibiotics) that are not derived from plants; they are derived from human, animal or microbiological sources. ABNs do not include ingredients for products regulated under the biologicals framework, or antibiotics.

Australian Register of Therapeutic Goods (ARTG): the reference database of therapeutic goods available in Australia. It provides information on therapeutic goods that can be supplied in Australia. Products may be registered or listed on the ARTG. If a therapeutic good is not entered on the ARTG it cannot be supplied in Australia, unless exempt.

British Pharmacopoeia (BP): is an annual published collection of standards for medicinal substances. It is also used as a reference for Australian approved ingredient names.

Complementary medicines: also known as 'traditional' or 'alternative' medicines; these include vitamin, mineral, herbal, aromatherapy and homoeopathic products. Complementary medicines may be either listed or registered, depending on their ingredients and the therapeutic claims made.

Consumer Medicines Information: the Consumer Medicines Information (CMI) is a leaflet that contains information on the safe and effective use of a prescription or pharmacist-only medicines.

Excipient: an ingredient or substance other than an active ingredient. An excipient is usually an inert or inactive substance used as an ingredient in therapeutic goods.

Hydration state: 'hydrate' is a term used to indicate that a substance contains water. A substance's hydration state is important to distinguish how much of the 'active ingredient' is present in a medicine.

INNs (International Non-proprietary Names): names maintained by the World Health Organization that identify pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognised and is public property.

Label: a product label is a display of printed information upon, or securely affixed to, the container, any intermediate packaging and primary packaging of a medicine.

Listed medicines: are considered low risk medicines. Medicines that are listed on the ARTG have been assessed against quality and safety, but not efficacy, criteria. This includes most complementary medicines. At the time of listing, sponsors must certify that the medicine meets a range of requirements. In particular, they must certify the medicine is eligible for listing, that the presentation is not unacceptable, that the medicine is safe for the purposes for which it is to be used, and that information or evidence is held to support any claim made in relation to the medicine. Listed medicines may only make limited therapeutic claims. Listed medicines can be identified by the presence of an 'AUST L' number on the medicine label.

Macrogol: is the INN for polyethylene glycol. Macrogols are synthetic polymeric substances that can be used as active ingredients (laxatives) or as excipients (solvents, ointment bases, film

coatings, lubricants). Macrogols when used as an excipient are used in both medicines and cosmetic products.

Nomenclature: a system of names assigned to objects or items.

Non-prescription medicines (over-the-counter medicines): medicines that can be purchased without a prescription, as follows:

- Pharmacist-only medicines that are available only from pharmacies with the provision of advice from a pharmacist prior to sale.
- Pharmacy-only medicines that are available for self-selection within a pharmacy.
- General sale medicines that are available in pharmacies, grocery and convenience stores.

Oxidation state: is a IUPAC naming convention that uses a Roman numeral to show the degree of oxidation of a chemical element.

Poisons Standard: the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) consists of decisions regarding the classification of medicines and poisons into Schedules (levels of public access) for inclusion in the relevant legislation of the states and territories.

Prescription medicines: medicine that must be prescribed by a healthcare professional with prescribing rights.

Product Information: a Product Information document (PI) provides healthcare professionals with a summary of the scientific information relevant to the safe and effective use of a prescription or pharmacist-only medicine.

Registered medicines: are evaluated for quality, safety and efficacy prior to being approved for market in Australia. High risk registered products include all prescription medicines and some specified products, such as sterile injectables. Lower risk registered products include non-prescription medicines and some complementary medicines. Registered medicines can be identified by the presence of an 'AUST R' number on the medicine label.

Trade name/brand name: means the commercial name given to goods by the manufacturer under which the goods are supplied.

1. Introduction

This Regulation Impact Statement (RIS) assesses options for changing Australian ingredient names used in existing therapeutic goods to align with international nomenclature systems.

The Therapeutic Goods Administration (TGA) proposes to update approved names (for both active and excipient ingredients) to bring them into line with international nomenclature as far as possible. Further associated name changes are also proposed - to improve consistency within Australian approved terminology and remove unharmonised, duplicate and out-of-date names.

In May 2013, TGA released a consultation paper[2] seeking feedback on this proposal, which affects 473 ingredient names. In total, 31 submissions[3] were received. As part of the consultation process, TGA also held focus groups with stakeholders to discuss the proposed name changes and seek feedback on implementation strategies. This RIS outlines options developed based on the issues raised during consultation.

2. The problem

2.1 Background

Ingredients that are used in the formulation of medicines can be classified as either active (where they have a therapeutic effect) or excipient ingredients. The names of **active** ingredients in a medicine's formulation must be included on the medicine label[4] and in the product's supporting documentation (for example pack inserts, promotional material, Product Information[5] and Consumer Medicine Information documents). Only a select number of **excipient** ingredients are required to be included on a label or in information provided to a consumer.

Companies that supply or manufacture therapeutic goods in Australia also maintain internal supporting documentation on a product's formulation details (both active and excipient ingredients). This includes manufacturing and regulatory documentation, Drug Master Files and adverse event databases.

Approved terminology is needed to ensure that names of ingredients used in medicines are accurate and consistent. Consistency in naming helps people search for information about medicines, allows health professionals and the public to compare similar goods and avoids the risk of confusion between goods.

International Nonproprietary Names (INNs) are the global reference for medicine ingredient names. The INN system was developed by the World Health Organization (WHO) and is maintained by member states, including Australia. The list of INNs is updated twice a year[6]. Since 2002, TGA has adopted INNs, where available, as its primary reference for new ingredient

[2] *Consultation: International harmonisation of ingredient names* – 13 May 2013 to 10 July 2013 <https://www.tga.gov.au/consultation/consultation-international-harmonisation-ingredient-names>
[3] Submissions received <https://www.tga.gov.au/submissions-received-international-harmonisation-ingredient-names>
[4] In accordance with the Therapeutic Goods Order No. 69 (TGO69) – General requirements for labels for medicines <https://www.comlaw.gov.au/Details/F2009C00264>
[5] Section 7D of the Therapeutic Goods Act 1989 <https://www.comlaw.gov.au/Series/C2004A03952>
[6] WHO | What's in a name? <http://www.who.int/features/2013/international-nonproprietary-name/en/>

names. However, there are ingredient names that were added to the TGA Business Services Ingredients Table prior to 2002 that are now not consistent with international naming practices.

Reference setting agencies (such as the WHO or the British Pharmacopoeia Commission) meet regularly to discuss the creation of new ingredient names or to update old names. These updates can include changes to the spelling or structure of existing ingredient names. Sometimes, new INNs are also created for long-existing substances that had previously been known by different names internationally. These types of changes have resulted in a number of ingredients on the Ingredients Table having different names than those now accepted as international best-practice.

In some cases, a new harmonised name was created on the Ingredients Table without removing the old name. This has resulted in more than one name for a specific substance and different products using different names for the same active ingredient. However, these differences are restricted to minor spelling variations.

Generally, the use of unharmonised, out-of-date or multiple ingredient names can create significant problems for the medicines industry, consumers and healthcare professionals. These problems include barriers to supplying a medicine in Australia, risks to consumer health and possible prescribing misadventure.

2.1.1 Medicines industry

The Australian pharmaceutical industry comprises bio-medical research, biotechnology firms, originator and generic medicines companies and service-related segments including wholesaling and distribution. In 2012–13, the Australian pharmaceutical industry reported a turnover of $23.4 billion[7]. With exports of $3.9 billion, pharmaceuticals were one of Australia's major manufactured exports that year[8].

The medicines industry also includes companies that manufacture and supply complementary medicines, such as vitamins or minerals. In 2012, the complementary medicine industry revenue was estimated as $3.5 billion and expected to grow[9].

Use of a unique Australian ingredient name creates an additional barrier to international trade for the Australian export industry. For example, the sponsor of a medicine in Australia may wish to also market that medicine internationally. Due to the lack of international harmonisation, the sponsor would need to perform additional steps to confirm that two ingredient names refer to the same substance. Although label and marketing materials are different for different countries, using a unique ingredient name results in additional labour time and complexity in developing this documentation. As raw materials may be sourced from multiple countries, manufacturing documentation may also need to be changed to align with Australian approved terminology. There would also be additional costs incurred in training staff to understand that both ingredient names refer to the same substance, and to maintain that training. These steps contribute to the barriers for Australian companies wishing to market products internationally.

Conversely, the need to use an out-of-date ingredient name in Australian medicine applications also imposes an additional burden on multinational companies wishing to market products in

[7] Australian Pharmaceuticals Industry Data Card 2014 <http://industry.gov.au/industry/IndustrySectors/PharmaceuticalsandHealthTechnologies/Pharmaceuticals/Documents/PharmaceuticalsDataCard.pdf>
[8] Pharmaceuticals Industry Profile <http://industry.gov.au/industry/IndustrySectors/PharmaceuticalsandHealthTechnologies/Pharmaceuticals/Pages/PharmaceuticalsIndustryProfile.aspx>
[9] Understanding Complementary Medicine <http://www.nicm.edu.au/health_information/information_for_consumers/understanding_cm>

Australia. For example, a sponsor must ensure that the Drug Master File and product information documents submitted to the TGA as part of a medicine application use Australian approved terminology. If the ingredient name is different to the one used internationally, this imposes additional production costs on both the active ingredient manufacturer and the sponsor of the finished goods, which are then passed onto the Australian consumer.

2.1.2 Consumers and healthcare professionals

The use of out-of-date names means that Australian consumers and healthcare professionals may be unfamiliar with international medicine ingredient names. This not only restricts the ability of consumers to access important medicine information internationally, but can also make it more difficult for doctors and nurses to keep up with international updates on medicine safety, adverse event information and emerging issues.

Out-of-date ingredient nomenclature can result in significant legal or health problems for Australians travelling overseas. This includes situations where some countries have restrictions on certain medications being brought in by travellers or where Australian travellers may have allergies to certain ingredients. For example, visitors travelling to the UK are required to check whether the medicines they are travelling with are licenced for use in the UK; must carry medicines in a correctly labelled container and bring a letter from their doctor in case the medicine is queried by customs officers or additional supplies are required[10]. Consequently, using a unique or out-of-date Australian ingredient name increases the risks:

- of confusion for customs officers when travellers are entering or leaving a country, leading to delays and possible confiscation of medicines; and
- that additional supplies of a medicine may not be found while overseas.

Out-of-date nomenclature also affects residents returning, and tourists travelling, to Australia. For example, phenobarbital (INN) is known as phenobarbitone in Australia. There are restrictions on the importation of barbituates into Australia, where illegal importation may attract criminal sanctions, including imprisonment and/or fines up to $825,000 [11]. Using out-of-date nomenclature requires Australian Customs officers to be aware of numerous names for an ingredient, increasing the risk of confusion and potentially resulting in avoidable border control problems.

TGA receives thousands of queries every year from travellers wishing to bring medicines for personal use into Australia. In 2013 the personal importation of medicines was the second most common query to the TGA Public Contact Team. In some of these queries, travellers have experienced border control problems, as they have been unaware of restrictions placed on their medicines, even though they have searched for information based on a specific ingredient name.

Healthcare professional representative groups have raised concerns that the use of more than one name for an ingredient can cause confusion in prescribing, increasing the risks of mis-dosing. For example, double-dosing can occur where a patient takes a product that uses one name for an ingredient as well another product containing the same ingredient under a different name. These risks of double-dosing are especially high for patients who visit more than one medical practitioner. There is limited evidence to show that these types of errors have occurred in Australia as a result of the current availability of more than one name for an ingredient; however, the consequences of such an error are severe and preventable. For example, 'lignocaine' is an ingredient used as an anaesthetic. 'Lignocaine' is an old British Pharmacopoeia (BP) name and is the approved name in Australia, however its INN (which has since been

[10] Visit Britain – Medical and health information <http://www.visitbritain.com/en/Travel-tips/Traveller-tips/Medical-and-health-information.htm>
[11] Importing Barbituates <http://www.border.gov.au/Factsheets/Documents/importingbarbiturates.pdf>

adopted by the BP) is 'lidocaine'. If not prescribed or administered correctly, this substance can have a severe effect on a patient's health[12].

The importance of clear and consistent ingredient naming was demonstrated in May 2013 when the Pharmaceutical Benefits Scheme (PBS) adopted new medicine terminology for prescribing and dispensing systems. The update included a change to the order of active ingredients in multi-ingredient products on dispensing software. This resulted in the order of ingredients for some products within the software not aligning with the order of ingredients on the relevant product labels. Pharmacists reported numerous dispensing errors in the three days following the data release[13], prompting a reversal of the data update.

2.2 Why is action needed?

2.2.1 Requirement to use approved ingredient names

TGA is responsible for regulating a range of therapeutic goods, including medicines and medical devices. Therapeutic goods must be entered in the Australian Register of Therapeutic Goods (ARTG) before they can be lawfully supplied in or exported from Australia, unless exempt from or otherwise authorised by TGA. The ARTG is an electronic system that relies on consistent ingredient terminology; consequently, TGA maintains approved terminology for use in therapeutic goods.

Regulation 2 of the *Therapeutic Goods Regulations 1990*[14] (the Regulations) defines the list of approved ingredient names maintained by TGA. This list of ingredient names includes those for chemical substances (Australian Approved Names [AANs] and Australian Biological Names [ABNs]) as well as names for herbal substances.

Approved ingredient names are published in the Ingredients Table on the TGA Business Services website[15]. These approved ingredient names are then used:

- when applications for registration and listing (including for export) of medicines are made to TGA
- in records of medicine formulations included in the ARTG
- on labels for medicines[16]
- in Product Information and Consumer Medicine Information[17] documents and
- other product documentation (such as advertising) where use of approved terminology is required.

[12] For example, lignocaine is used to treat life-threatening ventricular arrhythmias and if not administered correctly can result in patient death – see lignocaine HCl approved product information documentation <http://www.ebs.tga.gov.au>
[13] Confidential industry report – August 2013
[14] *Therapeutic Goods Regulations 1990* <https://www.comlaw.gov.au/Series/F1996B00406>
[15] TGA Business Services <http://www.ebs.tga.gov.au>
[16] Unless exempt, medicines are required to comply with the Therapeutic Goods Order No. 69 (TGO69) – General requirements for labels for medicines <https://www.comlaw.gov.au/Details/F2009C00264>. Inclusion of excipient ingredients on a label depends on the type of product (i.e. for injection, for ophthalmic use).
[17] PI/CMI search facility <https://www.tga.gov.au/picmi-search-facility>

If an ingredient name has been changed internationally, affected sponsors contact TGA to request its inclusion in the Ingredients Table as an approved name. Until this occurs, the international name cannot be used in Australian medicine labels or product information.

Although each country has specific labelling requirements, by changing ingredient names to INNs and updated pharmacopoeia names, Australian companies can benefit by more easily creating marketing and product information materials.

2.2.2 Improving information access and exchange

International harmonisation of ingredient names can help Australians who wish to find out more information on their medicines. The Internet is an increasingly common source of health-related information for consumers. Aligning Australian ingredient names with their international names will reduce confusion and help Australians more easily access international medicines information.

Australian consumers and healthcare professionals who travel internationally are also expected to benefit from harmonisation. Increasing consumers' familiarity with international ingredient names can reduce the risk of confusion when seeking medical advice/assistance in other countries, when explaining allergies to specific substances and when seeking legal advice on bringing personal medicines into a country. The harmonisation of active ingredient names could reduce the risk of adverse health or legal consequences for Australian travellers.

2.2.3 Clear ingredient naming

Australian terminology policy requires that the name used for an ingredient provides enough information to uniquely identify the substance. This can include information such as the substance's hydration state, the specific salt, or its stereochemistry (physical properties like stereoisomers, chiral states, etc.). By ensuring that only one name is used to specify an ingredient, the TGA supports the National Medicines Policy's objective for Quality Use of Medicines[18] by reducing confusion when selecting, prescribing or using medicines.

Quality use of medicines means that consumers and healthcare professionals select health management options wisely; choose suitable medicines if a medicine is considered necessary; and use that medicine safely and effectively. Using one name for an active ingredient reduces the risk of consumers accidentally double-dosing (taking a product that uses one name as well as a product with the same substance under a different name). Healthcare professionals would also not have to remember multiple names, reducing the risk of prescribing errors and severe health effects.

More specific names can also assist in the efficient evaluation and registration of new medicines. For example, an application for a product containing 10 mg/mL of apomorphine hydrochloride[19] under the current TGA naming approach refers to 10 mg/mL of apomorphine hydrochloride **hemihydrate** (which would contain more water, which is not therapeutically relevant, and less of the active component). However, as international conventions assume a substance is anhydrous (dry) if it does not include a hydration state, the sponsor may have intended to apply for 10 mg/mL of apomorphine hydrochloride **anhydrous**. This ambiguity then leads to the need for additional questioning and clarification from the sponsor.

[18] Quality Use of Medicines <http://www.health.gov.au/internet/main/publishing.nsf/Content/nmp-quality.htm>
[19] Used to treat Parkinson's disease

2.2.4 Improving functionality of the Ingredients Table and the ARTG

Some ingredients require the inclusion of a hyphen to accurately describe the structure of the substance (for example dl-alpha-tocopherol). Within the Ingredients Table, removal of hyphens from words previously inverted for searchability purposes (e.g. 'insulin — bovine'), will assist in reducing confusion with names that include hyphens necessary for their chemical structure. Removing multiple names for the same substance will also help in TGA's reporting activities, by making sure that the reports capture all products containing a specific substance.

The use of more than one name for an ingredient causes flow on problems to both TGA and external databases. The National e-Health Transition Authority (NeHTA), the Australian Government and state and territory governments are electronically connecting the points of care so that health information can be shared securely. NeHTA uses ARTG data to develop the Australian Medicines Terminology, a naming convention for describing medicines on prescribing, dispensing and ordering software across Australia. Due in part to inconsistencies on the ARTG, NeHTA systems have had to develop their own consistent naming which may be different from ingredient names on medicine labels. However, improving consistency within the ARTG will flow onto NeHTA systems and help reduce the potential for serious prescribing and administration errors.

2.3 What is proposed to change?

2.3.1 Summary of proposal released for consultation

The TGA compiled a list of active and excipient ingredient names that may need changing to harmonise with a more appropriate international reference and/or to align with TGA naming policies[20]. This review also included errors identified for correction (such as duplications and typographical errors). Table 1 summarises the types of changes proposed.

Table 1. Type of change

Change type	Source of change
Direct harmonisation with an INN. This includes the harmonisation of both the parent substance name as well as any derivatives.	INN
Changing a non-pharmacopoeia reference to a pharmacopoeia reference or INN.	International harmonisation
Inclusion of hydration state where appropriate. For example, inclusion of 'monohydrate' ('anhydrous' is the default, and does not need to be stated).	*International Non-proprietary Names Modified* [21] (INNM), Section IV, Paragraph 14, page 8.

[20] Outlined in the TGA approved terminology for medicines <https://www.tga.gov.au/publication/tga-approved-terminology-medicines>

[21] <http://www.who.int/medicines/services/inn/publication/en/>

Change type	Source of change
Where appropriate, using 'f' instead of 'ph', 't' instead of 'th' and 'e' instead of 'ae' or 'oe', 'i' instead of 'y', and avoiding the use of 'h' and 'k', e.g.: mesylate to mesilate oestrogen to estrogen cholecalciferol to colecalciferol	*Guidelines on the Use of INNs for Pharmaceutical Substances*, Annex 2, Paragraph 7. (INNM, Section II, Paragraph 7 gives examples)
Use of 'macrogol' terminology for synthetic polymers (rather than 'PEG')	INNM, Section IX, Paragraph 27, page 13.
Avoiding the use of isolated numbers, letters or hyphens (unless required for chemical structure).	*Guidelines on the Use of INNs for Pharmaceutical Substances*, Annex 2, Paragraph 6.
Using one name to refer to one substance and avoiding names that are in 'common' use (e.g. no use of brand names; a separate entry is required for each hydration state).	*Guidelines on the Use of INNs for Pharmaceutical Substances*, Annex 2, Paragraph 1.
Correct word order for salts and other derivatives	INNM
Use of common name for metals instead of Latin (e.g. use of 'iron' rather than 'ferrous'). Addition of oxidation state for a metal in a metallic compound where more than one oxidation state is possible but only a single oxidation state is present (e.g. iron (II) aspartate).	TGA naming policy[22] – the use of common names is more readily understood by consumers. The addition of the oxidation state better identifies the ingredient.

Dual-labelling

TGA noted that some of the identified ingredients were of high clinical significance and a change to their name would be associated with additional risks[23]. Dual-labelling was proposed for these ingredients to help transition to the new name and minimise the risk of the wrong medicine being used. Dual-labelling would require both the old name and the new name to be included on the label. Including two names on a label for the same ingredient is not uncommon for some medicines; the labels of many complementary and over-the-counter medicines include the approved ingredient name as well as its synonym (usually a more 'common' name) in brackets.

[22] Metal ingredients either use Latin names (such as 'cuprous' or 'cupric' for copper and 'ferrous' or 'ferric' for iron) or English common names. There is also no specific INN guidance on how to name metallic substances, and both common and Latin names for metals appear in INNs.
[23] This risk was calculated based on the combination of the prescription only status of the medicine and the degree of change in the ingredient name (i.e. prescription only medicines that only changed one letter in their ingredient name were not considered to be of 'high clinical risk').

Forty ingredient name changes are proposed for dual-labelling due to their higher clinical risk. Dual-labelling would be mandated for a period of time , after which a sponsor could start using the new name as the sole ingredient name.

2.3.2 Post consultation considerations

A summary of the issues raised during consultation is under Section 6 – Consultation. Among other feedback, stakeholders identified some discrepancies in the list of ingredients and requested that the order of dual-labelling be changed (new name first, followed by the old name). As a result, a number of additional entries were added[24] to the harmonisation list and some proposed changes to ingredient names removed or amended.

Adrenaline

The review of stakeholder comments identified that the substance 'adrenaline' (proposed to be changed to 'epinephrine' following a period of dual-labelling) is known by both names in some countries. For example, the BP name for adrenaline is now 'adrenaline (epinephrine)'. Therefore, in the United Kingdom, adrenaline products are labelled as 'adrenaline (epinephrine)' with no intent to change to 'epinephrine' as the sole name.

Stakeholders also identified significant risks associated with changing the name 'adrenaline' to 'epinephrine', especially around its potential to be mistaken for 'ephedrine'. For example, following a shortage of adrenaline syringe labels in an operating theatre in the UK, epinephrine labels were ordered. Twice in one day, anaesthetists who used ephedrine for treating hypotension labelled their syringes 'epinephrine'[25].

The revised proposal for adrenaline is to include both the old and new name with no end date, to best align with international practice. This proposal also extends to adrenaline derivatives:

- 'adrenaline (epinephrine) acid tartrate'
- 'adrenaline (epinephrine) hydrochloride'
- 'noradrenaline (norepinephrine)'
- 'noradrenaline (norepinephrine) acid tartrate monohydrate'

Final list for harmonisation

Following consideration of stakeholder comments, a final full list of 478 ingredient names is proposed for harmonisation. This list includes 269 active ingredients and 263 excipient ingredients[26]. The list also includes the 40 ingredients proposed for dual-labelling.

[24] The ingredients that were added to the list were either duplicate or parent entries of those already identified in the consultation paper. For example, 'Lignocaine hydrochloride' was included in the list for consultation, however, the parent ingredient entry 'lignocaine' was accidentally omitted.
[25] James, H. R. 'Ephedrine/epinephrine drug label confusion', Anaesthesia, 1998, Vol 53, issue 5. <http://onlinelibrary.wiley.com/doi/10.1046/j.1365-2044.1998.04771.x/pdf>
[26] 54 of the 263 excipient ingredients are also present as active ingredients in some products.

3. Objectives

The first objective of this harmonisation activity is to maintain clarity and consistency in ingredient naming (as far as possible) to support quality use of medicines. Unambiguous and internationally consistent ingredient names help health professionals and the public to compare similar therapeutic goods and avoid confusion between goods. Consistency in naming also supports the quality use of medicines by:

- minimising the risk of prescribing, dispensing and self-selection errors
- enhancing consumer safety (through easier international information sharing) and
- avoiding consumer confusion and the inappropriate use of medicines.

The second objective is to minimise administrative costs for industry, thereby supporting the commercial viability of supplying medicines to Australian consumers and internationally. The use of internationally harmonised ingredient names in Australia can assist industry by reducing costs associated with preparing marketing and product information materials. Internal consistency within the Ingredients Table can also benefit industry as it assists TGA in more efficiently assessing applications for new medicines or variations to existing products.

4. Options to achieve objectives

This RIS considers the following options for the list of 478 active and excipient ingredient names proposed for harmonisation:

Option 1: Status quo – No changes would be made to ingredient names.

Option 2: Mandatory adoption of harmonisation with international protocols - the full proposal – Adopt all the proposed name changes (478 ingredient names changed). The old ingredient names would be removed from the Ingredients Table and sponsors would only be able to use the new ingredient names.

Option 3: Mandatory adoption - a reduced proposal – This option proposes to reduce the full list of name changes, based on issues raised during consultation. This option focusses on removing ingredient name changes that have not been adopted consistently in the international market:

a. Maintain status quo for metal containing ingredients – No Latin-to-English name changes would be made to metal-containing ingredients.

b. Maintain status quo for sunscreen ingredients – No changes would be made to names that are used for active ingredients in current TGA-regulated sunscreens.

c. Maintain status quo for some excipient ingredients – No changes would be made to some excipients where the source reference did not apply this terminology.

d. Maintain status quo for macrogol excipient ingredients – No changes would be made to macrogol ingredients only used as excipients.

Under this option, 336 ingredient names would change.

Option 4: Mandatory adoption – only those changes based on direct harmonisation of INNs or references plus changes of high clinical significance – This option proposes to further reduce the full list by only implementing name changes where the replacement name has an international reference or an INN which has not been modified, plus a number specific ingredients identified as being of high clinical significance.

Under this option, 160 ingredient names would change.

Option 5: Voluntary name changes – New ingredient name entries would be created on the Ingredients Table and sponsors could voluntarily move to using the new names or continue to use the old ingredient name. Consequently, different products could use different ingredient names on their labels when they are actually referring to the same substance. This voluntary approach can be applied either to the full proposal (478 names) or to a reduced list.

A transition period would be needed for Options 2, 3 and 4. Two transition options are presented:

- **Transition Option (i):** proposes a **three year** transition period for changing ingredient names.
- **Transition Option (ii):** proposes a **four year** transition period for changing ingredient names.

For both transition options, medicines with ingredients identified as of 'high clinical significance' would be dual-labelled with both the old and new name for an additional three years. Following this period, sponsors could then start using the new ingredient name as the sole name.

5. Impact analysis

There are assumptions and limitations underpinning the impact analysis and the conclusions of the analysis must be regarded as indicative rather than as definitive.

Industry compliance costs have been outlined below and quantified wherever possible. TGA has made assumptions based on general information, ARTG data on existing products, stakeholder feedback from the IHIN and medicine labelling consultations.

In accordance with Office of Best Practice Regulation requirements, the costs below have been costed over a 10 year period and presented as an average annual impact.

Table 1. Summary of Regulatory Burden and Cost Offset Estimates for all options

Average annual regulatory costs (from business as usual) ($million)				
Change in costs ($ million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Option 1 (status quo)	0	0	0	0
Mandatory adoption				
Option 2(i) (3 year transition)	$0.91	0	0	$0.91
Option 2(ii) (4 year transition)	$0.23	0	0	$0.23
Option 3(i) (3 year transition)	$0.73	0	0	$0.73
Option 3(ii) (4 year transition)	$0.13	0	0	$0.13

Average annual regulatory costs (from business as usual) ($million)				
Change in costs ($ million)	**Business**	**Community Organisations**	**Individuals**	**Total change in cost**
Option 4(i) (3 year transition)	$0.51	0	0	$0.51
Option 4(ii) (4 year transition)	$0.12	0	0	$0.12
Voluntary adoption				
Option 5	0	0	0	0
Cost offset ($million)	**Business**	**Community Organisations**	**Individuals**	**Total by Source**
	$0.91	0	0	$0.91
Are all new costs offset? Yes, costs are offset by the savings that were identified by the Low Value Turnover Exemption Scheme RIS				
Total (Change in costs - Cost offset) ($million) $0				

5.1 Option 1 – Status quo

Option 1 proposes that no changes occur to ingredient names under the harmonisation activity (status quo). Under this option, industry would continue to use the ingredient names that have previously been approved for use in medicines. The current inconsistencies in the TGA Ingredients Table would remain and these non-harmonised medicine ingredient names would continue to be used in Australia. The problems associated with this lack of harmonisation would continue (as outlined in Section 2 – The problem).

Under Option 1 there are no direct compliance costs for industry. However, to establish a baseline, TGA analysed the information it holds on medicine label and product information changes (see Appendix A).

5.2 Option 2 – Mandatory adoption – the full proposal

Option 2 proposes to change the names of 478 ingredients. These new names would be the only Australian approved names for those substances and the old names would be removed from use.

This option affects **18,758 ARTG medicine entries** (approximately 54% prescription, 12% OTC, 35% Listed) and **1,029 sponsors**. In some ARTG entries more than one ingredient name would be changed.

5.2.1 Impact on the medicines industry

Appendix A outlines the expected costs to industry for Option 2. Depending on the transition timeframe, Option 2 is expected to cost industry **$0.91M** (3 year transition) or **$0.23M** (4 year transition) per annum over 10 years.

Companies would be affected differently depending on what type of product they sponsor. Table 2 outlines the type of impact expected for each type of product. These impacts only apply to changes to active ingredient names and a small number of excipient ingredients (25% of the proposed changes).

Table 2. The type of product affected and the type of impact (for changes to active ingredients and a small number of excipients only)

Type of product	Type of impact
Prescription medicine	Update to PI/CMIs
	Update to product label (where applicable)
Over the counter medicine (including some sunscreens)	Update to PI/CMIs, where applicable (restricted medicines, pharmacist-only medicines)
	Update to product label, pack inserts, promotional material (where applicable)
Complementary medicine (both registered and listed)	Update to PI/CMIs, where applicable (restricted medicines, pharmacist-only medicines) Update to product label, pack inserts, promotional material (where applicable)
Export Only medicine	Negligible impact[27]

Product labels and supporting documentation will be affected differently, depending on how the name of the active ingredient has changed. Most of the ingredient name changes involve the change of one letter, the addition/removal of a hydration state, removal of hyphen or a change in word order. It has been assumed that the proposed ingredient name changes would therefore not require redesign of the label.

Some medicines use the active ingredient name as part of the product's trade name (also known as product name or proprietary name). This proposal will harmonise the names of ingredients contained within medicines, not the trade names of the medicines themselves. However, to avoid confusion, the sponsor of such a product may wish to change the trade name to match the harmonised name. The decision to change a trade name as a consequence of an ingredient name change would be a voluntary commercial decision for the sponsor.

Following a one-off cost, Option 2 is expected to provide an ongoing saving to sponsors. This arises from the reduction of costs associated with developing and varying recurring documentation between Australia and other markets (e.g. advertising and marketing materials, supporting documentation). This option will therefore result in a small reduction in barriers to

[27] Some export only sponsors may wish to update 'Certificate of Pharmaceutical Product' documentation, however this does not need to be resubmitted to the TGA.

trade for individual companies, however it is not expected to have a noticeable effect on the market overall.

A longer transition period would allow sponsor companies to more easily incorporate these ingredient name changes into business-as-usual (BAU) practices. For example, it is assumed that approximately 50 per cent of affected products would change their label within a three year period as part of BAU. The remaining 50 per cent of products would need to bring forward any planned changes to labels and other documentation to avoid having to pay twice for changes (once for the regulatory changes, once for the business need). Appendix A outlines the costs of name changes to sponsors under both a three and four-year transition period.

5.2.2 Impact on consumers and healthcare professionals

During consultation, most stakeholders agreed that international harmonisation of ingredient names would generally benefit consumers. Once consumers are familiar with the new ingredient names, benefits include improved access to information and reduced risk of confusion with medicines when travelling overseas. Similarly, ingredient name harmonisation is also expected to assist healthcare professionals in the long term. This activity will help Australian practitioners who are not aware of international naming by improving their access to information. However, due to the complexity of how consumers and healthcare professionals interact with medicines and ingredient names, it is not possible to isolate and quantify the benefits of the proposed harmonisation activity.

Improving consistency within TGA databases can also improve the consistency of names used in prescribing and dispensing software and potentially reduce the costs associated with maintaining these systems. The NeHTA e-Health program includes the development of medicines terminology derived from the ARTG and other TGA databases. Using one name for an ingredient and improving TGA database consistency allows easier alignment for the NeHTA databases. For example, using only one name for an ingredient would reduce the risk of the ingredient name on a label differing from the name on the prescribing software. These benefits then flow onto the users of prescribing, dispensing and ordering software reliant on NeHTA terminology.

During the transition period, consumers and healthcare professionals will gradually start to see changes to ingredient names on the labels of affected products, in Product Information and Consumer Medicine Information documents, as well as in prescribing and dispensing software[28]. Most of the proposed name changes are to excipient ingredients (75%), which will have minimal impact as this information is not often included on labels and is not visible in the public view of the ARTG. Where changes are made to active ingredients, many involve limited label changes (such as changing from amox**y**cillin to amox**i**cillin or the removal of a hyphen within the ingredient name).

Stakeholders raised safety concerns about the transition periods for ingredient name changes, especially where:

- one sponsor has changed their labels at the beginning of the transition period, and
- another sponsor of a medicine with the same active ingredient chooses to delay the change until the end of the transition period.

There are products currently available in Australia that use different names for the same substance (e.g. amox**y**cillin versus amox**i**cillin). As described earlier, there is limited evidence to show that medication errors have occurred in Australia as a result of the current availability of

[28] The ingredient names used in prescribing and dispensing software is not regulated by TGA. However, TGA will work with these stakeholders to assist in changes, where required.

more than one name for these ingredients. However, TGA acknowledges that increasing the number of substances that have multiple ingredient names also increases the likelihood of prescribing errors. Dual-labelling has also been proposed for substances of high clinical significance to help reduce the risk of confusion.

Industry, healthcare professional and consumer stakeholders all noted that communication and education activities are required to reduce the likelihood of such errors. Section 8 - Implementation and review provides further information on proposed communication strategies. Due to these proposed activities, there appears to be little difference in risk to consumers between a three and four-year transition period.

There are significant benefits to industry, healthcare professionals and consumers from Option 2. However, during consultation, stakeholders noted that some of the proposed ingredient name changes may result in a lack of harmonisation between Australian nomenclature and the most widely used international terminology. Therefore, the net outcomes would be significantly improved by removing from the proposal those ingredient names that have not been adopted consistently in the international market.

5.3 Option 3 – Mandatory adoption – a reduced proposal

Option 3 proposes to reduce the full list of name changes, based on the issues raised during consultation. This option removes ingredient name changes that have not been adopted consistently in the international market. Option 3 comprises four sub-options (a-d) which are described below.

5.3.1 Option 3a – Maintain status quo for metal-containing ingredients

TGA naming policy requires new metal ingredients to use common English names (rather than Latin names) and include oxidation states - for example, 'copper(I)' and 'iron(II)' rather than 'cuprous' and 'ferrous'. This approach is applied as common English names are more easily understood by consumers.

Overall, INN policy prefers the use of English names for substances. However, there is no specific INN policy for metal names. Some existing INNs for metal-containing ingredients include English names and some use Latin names. The TGA Ingredients Table also currently includes some metal ingredients in English and some in Latin; however, since 2006, new ingredients are provided with English names.

Option 3a would remove from the full proposal changes where a Latin metal name was amended to its English name. Option 3a would also remove any changes where an oxidation state was included for a metal-ingredient (a flow-on effect from the Latin to English name change).

Due to existing TGA labelling requirements, many preparations containing trace elements as mineral supplements are already labelled with the quantity of the element in each dose. For example, a product containing 'ferrous fumarate' could be labelled as 'iron 5mg (as ferrous fumarate)'. As this option does not affect labelling requirements, under Option 3a, labels would still need to show how much iron, copper or manganese (using their English names) is in each dose of a product.

5.3.2 Option 3b – Maintain status quo for active ingredients used in TGA-regulated sunscreen products

In Australia, most sunscreen products are regulated as therapeutic goods with the majority of these being primary sunscreens with a Sun Protection Factor (SPF) rating of 4 and entered on the ARTG as listed medicines[29]. Secondary sunscreens that are excluded from regulation under the *Therapeutic Goods Act 1989* are regulated as cosmetics by NICNAS.

However sunscreens are regulated by most countries as cosmetics, not therapeutic goods. In these countries, sunscreen products use European International Nomenclature of Cosmetic Ingredients (INCI) names for the active ingredients. Similarly, for sunscreens regulated by NICNAS, the names of the ingredients on the label must be either their English names or their INCI names[30].

TGA applies the INN naming policy to all ingredients, if an INN exists. This approach is also used for sunscreen ingredients because these ingredients can be included in other therapeutic goods (for example, arthritis creams).

Option 3b would reduce the full proposal by removing proposed changes from an INCI or USAN name to an INN for ingredients that are solely used as actives in sunscreens (i.e. not used in any other type of therapeutic good). Sunscreen active ingredients that are present as actives in arthritis creams would still change their name to an INN name; and sunscreen ingredients where the INCI reference name was updated by the reference-setting organisation would change to the new updated name.

Importantly, some sunscreen active ingredients may be associated with adverse reactions[31]. Although the TGA proposes a comprehensive communication strategy for ingredient name changes, there is still a risk of consumer confusion because ingredients in cosmetic sunscreen products would continue to use INCI names on labels. By reducing changes to existing sunscreen ingredient names, Option 3b would significantly reduce the impact on consumers otherwise resulting from proceeding with Option 2.

5.3.3 Option 3c – Maintain status quo for some excipient ingredients

TGA seeks to apply INN naming policies to both new active and new excipient ingredients. These naming policies include the application of INN spelling conventions (using 'f' instead of 'ph','t' instead of 'th', 'e' instead of 'ae' etc). However, many excipient ingredients do not have INN names and in these instances other international naming references are used (e.g. BP, United States Pharmacopeia (USP)).

Several of the proposed changes applied INN spelling conventions to ingredient names from other references (such as pharmacopoeias). For example, the USP name cyclome**th**icone (an excipient also used in cosmetics) was proposed to be changed to cyclome**t**icone to align with the spelling for other silicone-based polymers (such as dimeticone and simeticone, which have INNs). As there is no INN or BP entry for cyclome**t**icone, the new name would pre-empt international changes.

[29] *Australian regulatory guidelines for sunscreens (ARGS)* <https://www.tga.gov.au/publication/australian-regulatory-guidelines-sunscreens-args>

[30] Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991 <https://www.comlaw.gov.au/Details/F2008C00244>

[31] Many stakeholders raised concerns about the potential for adverse reactions with sunscreen ingredients. A search of the TGA Adverse Event Database <https://www.tga.gov.au/daen/daen-entry.aspx> revealed 15 reports of adverse events associated with sunscreens between July 2012 and June 2013. However, these results may also be due to non-sunscreen ingredients.

Option 3c would remove from the full proposal excipient ingredients that have had INN spelling conventions applied to non-INN reference names. For example, many international references continue to use 'cyclomethicone' (instead of 'cyclometicone') or 'lauryl' (instead of 'lauril'). These name changes have been removed under Option 3c. However, the new spelling of 'dimeticone' and 'simeticone' has been widely accepted by INN and several non-INN references. Under Option 3c, the removal of the 'h' in 'dimethicone' would still occur.

Although cyclomethicone and sodium lauryl sulfate are present in many medicine and cosmetic products, in many cases only cosmetic products include these ingredients on the label. In rare situations where these ingredients **are** included on medicine labels, Option 3c would avoid ingredient name misalignment between medicine and cosmetic products.

5.3.4 Option 3d – Maintain status quo for macrogol excipient ingredients

TGA applies INN 'macrogol' terminology to synthetic polymeric substances. Synthetic polymeric substances can be:

- active ingredients – polyethylene glycols (PEGs), used as laxatives and
- excipients – ceteths, oleths etc, used as emulsifiers in medicines and cosmetics.

INN macrogol names consist of a stem name (macrogol, lauromacrogol) and a number that designates the substance's average molecular mass (for example, macrogol 500).

Not all synthetic polymeric substances have individual INN stem names. For example, there is an INN stem for ceteths (cetomacrogol) but not for oleths (the INN stem would likely be olomacrogol, if created). Changing all synthetic polymeric substance names to macrogol terminology would in some cases pre-empt INN action. As many of these substances are also present in cosmetic products, changes to excipient synthetic polymeric substances may result in a misalignment between medicines and cosmetic products.

Option 3d would remove from the full proposal macrogol changes to excipient ingredients only. Ingredients that are used as actives in medicines will still change to macrogol terminology, where an INN stem exists for that specific synthetic polymeric substance.

5.3.5 Impact of Option 3

Table 3 outlines the total number of ingredients removed from the full proposal under this option.

Table 3. Number of ingredients removed from the full proposal under Option 3

Option	Type of change	Number of ingredients removed from full proposal
Option 3(a)	Status quo for metal-containing ingredients	27
Option 3(b)	Status quo for sunscreen active ingredients	9
Option 3(c)	Status quo for some excipient ingredients	7
Option 3(d)	Status quo for macrogol excipient ingredients	100
Combined Option 3(a-d)		143

Under this option, 336 ingredient names would change. This option affects **17,886 ARTG entries** (55% prescription, 11% OTC, 34% Listed) and **972 sponsors**.

Appendix A outlines the costs to industry for Option 3. Depending on the transition timeframe, Option 3 is expected to cost industry **$0.73M** (3 year transition) or **$0.13M** (4 year transition) per annum over 10 years.

Compared to Option 2, the benefits to industry, healthcare professionals and consumers are increased under Option 3. By removing these ingredients from the proposal, the compliance costs to industry (e.g. updating labels) are reduced. As the removed ingredients are not consistently adopted internationally, Option 3 also minimises potential qualitative impacts on industry, consumers and healthcare professionals. The impact of the three and four-year transition period to industry, healthcare practitioners and consumers is similar to that outlined earlier, under Option 2.

Due to the qualitative gains from harmonisation, this option is expected to result in an overall net benefit to consumers, healthcare professionals and industry once the name changes are embedded in Australian nomenclature.

5.4 Option 4 – Mandatory adoption – Direct harmonisation of INN/reference and substances of high clinical significance

During consultation, stakeholders raised concerns about proposed name changes that included a 'modification' in the name. For example, a name was modified from the international reference to include the name of a salt or a hydration state.

Option 4 proposes to further reduce the full list of name changes. This option comprises only those changes where the replacement name has an international reference or an INN that does not require modification, plus those ingredients identified as being of high clinical significance.

The WHO usually creates only an INN for the active part of the molecule, to avoid multiple entries where several salts, esters or other derivatives are used[32]. In such cases, individual member countries modify INNs by including further information in the name (such as the salt or hydration state)[33].

TGA naming policy requires that ingredients be named in a way that clearly and unambiguously identifies the substance being named. Consequently, TGA allocates individual names for each derivative of a substance. For example, where a substance is used in the form of a salt or ester, that salt or ester is included in the name. In situations where there are different hydration states for substances, separate entries are included in the Ingredients Table, with anhydrous (dry or containing no water) as the default type (i.e. if no hydration state is included in the name, the ingredient is anhydrous). The majority of modifications are due to the inclusion of this type of additional information, however some modifications also propose minor typographical changes (i.e. removing hyphens, e.g. 'sodium phosphate – monobasic' to 'sodium phosphate monobasic'.

5.4.1 Impact of Option 4

Under this option, 160 ingredient names will change. This option would affect **6,478 ARTG entries** (47% prescription, 13% OTC, 29% Listed) and **350 sponsors**.

[32] WHO Guidance on INN <http://www.who.int/medicines/services/inn/innguidance/en/>
[33] WHO International Nonproprietary Names Modified <http://www.who.int/medicines/services/inn/INNMreview%20paperWkDoc167_Feb06_3_.pdf>

Appendix A outlines the costs to industry for Option 4. Depending on the transition timeframe, Option 4 is expected to cost industry **$0.51M** (3 year transition) or **$0.12M** (4 year transition) per annum over 10 years.

If this option is adopted, some of the ambiguity in ingredient naming will remain within the TGA Ingredients Table. As the number of international pharmacopoeia references that include the degree of hydration within ingredient names increases, the risks of confusion between Australian ingredient names and those used internationally increases. For example, occasionally Australia experiences shortages of medicines. Additional medicine supplies are then sourced from other countries. For higher risk medicines, the packaging may be altered to reduce the risk of confusion for Australian consumers or healthcare professionals. Under this option, there is increased risk of confusion for those medicines where labels were not altered and a different hydration state has been used to determine the amount of active ingredient per dose.

Overall, there is little difference in the compliance costs to industry between Options 3 and 4. Due to the potential for ambiguity and confusion, the qualitative benefits have been significantly reduced under Option 4.

5.5 Option 5 – Voluntary name changes

Option 5 proposes that ingredient name changes be applied voluntarily. Therefore, sponsor companies could chose to move over to using the new ingredient name on labels and product information or continue to use the old name. The new harmonised ingredient names would be added to the TGA Ingredients Table, but the old name would only be removed if all sponsors had moved over to the new name.

Out of the full proposal to change 478 ingredients, **128** of the new names already exist on the Ingredients Table (**27%**) and **350** new names would be added.

5.5.1 Impact of Option 5

Under Option 5, existing inconsistencies in the TGA Ingredients Table would be magnified. Many of the new ingredients have been identified as being of high clinical significance. For example, both colaspase (the current Australian Approved Name) and asparaginase (the new name) could be used on different medicine labels, depending on the sponsor's preference. If a sponsor wished to use the new name, there would also be no dual-labelling requirement to show that asparaginase used to be known as colaspase in Australia. The old name would only be removed from use once all products using that name move to the new ingredient name. However, it is possible that both old and new names for the same substance could remain in use indefinitely.

There would be no compliance costs imposed on sponsors under this option. However, its adoption would increase the complexity of the registration and listing process for new medicines, resulting in potential increased costs to industry. This option would be especially problematic for changes where the old name is proposed to change to a new meaning. For example, 'carbidopa' is proposed to change to 'carbidopa monohydrate' (contains water). 'carbidopa anhydrous' would become just 'carbidopa' (does not contain water). Under Option 5, there is a greater risk that some products would show inaccurate amounts of the active ingredient if a structured transition process is not implemented.

Under Option 5, the risk of confusion for consumers and healthcare professionals would be significantly increased. By increasing the use of multiple names for a single substance, healthcare professionals are more likely to make prescription mistakes (where the wrong medicine is prescribed or administered) and consumers are at greater danger of accidentally double-dosing (taking two medicines containing the same substance but identified using different names). These risks are especially high in situations where the old and new ingredient names are not similar (i.e. colaspase versus asparaginase).

These risks could be significantly lowered if this option were only applied to a subset of ingredient names, for example for excipient ingredients only. As excipient ingredients are not usually included on product labels, using more than one name for an excipient would have very little effect on prescribing or taking medicines. As most compliance costs arise due to label changes, the cost to industry for this sub-option would be in effect identical to costs outlined in earlier options.

Although there are no quantified compliance costs, there is a high qualitative cost for Option 5. Due to the significant increase in confusion and the potential danger to consumer health and safety, Option 5 is associated with an overall net cost to industry, consumers and healthcare professionals.

6. Consultation

In May 2013, TGA consulted[34] on a proposal to change 473 ingredient names. Thirty-one submissions were received[35] from the therapeutic goods industry, and healthcare professional and consumer organisations (see Appendix C). The TGA also held focus groups with some stakeholders to discuss the proposed name changes and seek feedback on implementation strategies.

Overall, consultation responses supported international harmonisation of ingredient names, in principle. Healthcare professional and consumer organisations stated that harmonisation would reduce ambiguity and confusion by providing international consistency. With a few exceptions, most stakeholders agreed that the proposed changes would help the pharmaceutical industry provide Australians with medicines. Some industry stakeholders asserted that the proposed changes would enhance and improve patient safety when selecting over-the-counter medicines (with the exception of issues outlined below).

The issues raised in the submissions are grouped into two main themes:

- the potential lack of harmonisation with international naming and
- the implementation of ingredient name changes.

6.1 Potential lack of harmonisation

6.1.1 Unique names

Some stakeholders raised concerns that TGA was changing existing harmonised ingredient names to non-harmonised names. The consultation paper provided a table of 473 existing names and included the proposed new name and the old and new references. In 113 cases (24%), the new reference column was blank (see Table 4 for an example).

Table 4. Example of proposed ingredient name change in consultation paper

ID	Current Name	Current Ref	Proposed Name	New Ref
52796	Cholecalciferol	BP	colecalciferol	

[34] Consultation: International harmonisation of ingredient names – 13 May 2013 to 10 July 2013 <https://www.tga.gov.au/consultation/consultation-international-harmonisation-ingredient-names>
[35] Submissions received: international harmonisation of ingredient names <https://www.tga.gov.au/submissions-received-international-harmonisation-ingredient-names>

Some stakeholders interpreted this blank space to mean that the new ingredient name was unique and did not have an international reference. This blank space instead meant that the current reference had updated the old name and TGA was proposing to align with this update (hence a change to the current reference was not needed). In the cholecalciferol example above, the BP would remain as the ingredient name reference.

6.1.2 Hydration states and modified names

Many stakeholders raised concerns about including the hydration state in an ingredient name. Some stakeholders claimed that including a hydration state would result in unique Australian names. Option 4 has been included in this RIS in response to these concerns.

Mostly, these concerns were related to whether this hydration state would have to be included on a label, and the difficulties in fitting the extended name on the label. Some stakeholders claimed that this information would not help consumers or healthcare professionals and would instead cause confusion. The majority of current approved ingredient names include the accurate hydration status in the name. This proposal only changes those ingredients that did not have this accurate information.

Some submissions were specifically concerned about the change from 'lactose' to 'lactose monohydrate', and whether label statements like 'lactose free' would be affected. Although the ingredient 'lactose' will be changed to include its hydration state on the Ingredients Table, the word 'lactose' would still be used on a label. A product contains 'lactose' regardless of whether it contains 'lactose monohydrate' or 'lactose anhydrous'. The exact amount of lactose (as an excipient) is rarely disclosed on the label of a medicine. Therefore, a label statement of 'contains lactose' or 'lactose free' would remain the same.

6.1.3 Metal naming (English names and oxidation state)

Some industry stakeholders raised concerns that changing metal-containing ingredient names to English would create unique Australian names. Stakeholders asserted that there would be no advantage to changing metal names as the existing names did not pose a health concern and current labelling requirements ensured that the English name of the metal was included on the label. Industry and healthcare professional stakeholders also asserted that there was no benefit to the consumer or practitioner from including the metal oxidation state in the name. Option 3 has been included in this RIS in response to these concerns.

6.1.4 Use of INN terminology for sunscreen active ingredients

Industry stakeholders raised concerns that changing sunscreen active ingredient names to INN or pharmacopoeia nomenclature would result in a lack of international harmonisation with most countries. Stakeholders also raised concerns about the potential lack of consistency within Australia, as NICNAS would continue to use INCI naming for secondary sunscreen products. Stakeholders asserted that some sunscreen ingredients are associated with allergies and this inconsistency could increase risks to Australian consumer health. Option 3 has been included in this RIS in response to these concerns.

6.1.5 Use of INN terminology for excipient ingredients

Industry stakeholders raised concerns about using INN spelling conventions for excipient ingredient names. These stakeholders asserted that INNM naming guidelines should not be used for excipients where there is a more authoritative reference that can be used as the naming reference (such as a pharmacopoeia). These comments were specific to ingredients such as 'cyclomethicone', or 'sodium lauryl sulfate'. It was asserted that such pre-emptive action would result in a lack of harmonisation for no benefit.

Stakeholders also noted that excipients like cyclomethicone are present in many cosmetics and included on cosmetics labels. Stakeholders asserted that where these excipients are included in medicine labels (i.e. injections), such INN spelling changes may result in consumer confusion.

Option 3 has been included in this RIS in response to these concerns.

6.1.6 Macrogol terminology

Some industry stakeholders raised concerns that changing all synthetic polymeric substance names to macrogol terminology would pre-empt INN action in some cases. Some stakeholders noted that not all of these substances had INN stems.

One submission supported changing pure polyethylene glycols to macrogol terminology. However, this stakeholder asserted that using this naming for other synthetic polymeric derivatives (usually used as excipients) would result in a lack of harmonisation with cosmetic products. This stakeholder asserted that the active use of an ingredient should be prioritised over the excipient use, as it will appear on the label and needs to be meaningful to consumers.

Industry stakeholders also noted that there was a lack of consistency between how international standards define macrogol terminology (i.e. the average molecular mass of the polyethylene glycol portion).

Option 3 has been included in this RIS in response to these concerns. An updated numbering method has been applied for these changes.

6.1.7 Specific ingredients where INNs may not be appropriate

Adrenaline and noradrenaline

Adrenaline and noradrenaline are historic BP names. The consultation paper proposed to change these names to their INN counterparts (epinephrine and norepinephrine). The paper also proposed to dual-label adrenaline and noradrenaline products with both the new and old names for a total transition time of five years before moving to the INN as the sole name.

Most stakeholders (industry, government and healthcare professional) raised concerns about this proposed change. These concerns focussed on potential risks to patient safety because of the substance's high clinical significance and possible confusion between epinephrine and ephedrine. Some stakeholders stated that an intense education program and five year dual-labelling requirement would not be sufficient to mitigate these risks. Some stakeholders also noted that the current BP entries for adrenaline and noradrenaline include both the old names and the new INNs (epinephrine and norepinephrine).

In response, adrenaline and noradrenaline are proposed to be dual-labelled (dual-named) with no end date, consistent with the UK approach.

Menthol

The original proposal in the consultation paper was to change the ingredient name 'menthol' (a USP name) to 'racementhol' (INN). Stakeholders also noted that if 'racementhol' was adopted, a new entry would need to be created for 'levomenthol' since the USP definition of 'menthol' covers both physical states of the substance (racementhol and levomenthol).

Menthol is an ingredient common both to food and medicines. Stakeholders therefore raised concerns that the name change may result in consumer confusion and a lack of harmonisation between regulators. Stakeholders asserted that 'menthol' was the name used in therapeutic products internationally and there was limited benefit in knowing which menthol stereoisomer was used in a product (racementhol versus levomenthol).

In response, menthol was removed from the full proposal.

Fish oils

The consultation paper proposed to change 'docosahexaenoic acid' (DHA) (a Martindale name) to 'doconexent' (INN). The paper also proposed to change 'eicosapentaenoic acid' (EPA) (a Merck Index name) to 'icosapent' (INN). EPA and DHA are fatty acids (present as triglycerides) in fish oils and other oils derived from natural sources.

Stakeholders raised concerns that these changes would result in a lack of harmonisation as EPA and DHA terminology is commonly used in the literature internationally. Stakeholders also asserted that the proposed change would result in consumer confusion for little benefit.

Further consideration revealed that EPA and DHA are components of ingredients (fish oils), not ingredients themselves. TGA policy does not apply INN naming to components of ingredients. Therefore INN nomenclature may not be appropriate for EPA and DHA.

As EPA and DHA are technically not ingredients, they have been removed from the full proposal.

6.2 Implementation

Stakeholders provided extensive feedback on implementation strategies. Much of this feedback has been incorporated into the proposed implementation process (see Section 8 – Implementation and review). The main themes are outlined below.

6.2.1 Fee waivers

Several stakeholders noted the costs associated with label changes and requested that TGA provide fee waivers for any required updates to ingredients databases, the ARTG, PIs and CMIs.

In response, it will be clarified that changes to ARTG entries initiated by TGA are not fee based. Therefore updating the ARTG entry and the resulting updates to labels, PIs and CMIs will not incur a fee if the only change is the harmonisation of the ingredient name. Alternatively, to reduce the impact on businesses, the use of a transition period is intended to minimise the costs of ingredient name updates by allowing the incorporation of changes to the ARTG/PIs/CMIs as part of business-as-usual processes.

6.2.2 Timing

The consultation paper proposed a two year transition period for ARTG/label/CMI/PI changes. For substances proposed to be dual-labelled, an additional three years was suggested for a total dual-labelling period of five years.

Most industry stakeholders stated that a two year transition period was insufficient to update labels and supporting documentation and to allow the use of excess stock. Industry stakeholders proposed alternative transition periods ranging between three to five years. The majority of consultation responses agreed that timeframes should align with other TGA activities that are expected to affect sponsors and the community (such as the labelling review).

Some stakeholders noted that an extended transition period may increase risks to patient safety, especially if name changes are implemented on prescribing software before labels are changed (and vice versa). Risks of consumers inadvertently double-dosing may arise where multiple brand products are available for the same ingredient and some sponsors update their labels before other sponsors.

In response, two transition options have been developed (three years and four years) and a communication program is proposed to reduce the risks associated with the transition (see Section 8 – Implementation and review).

6.2.3 Dual-labelling

The consultation paper proposed that substances be dual-labelled with the old name first, followed by the new name. Most stakeholders preferred the opposite order for labelling – that the new ingredient name be listed first, followed by the old name in brackets. For example, 'lignocaine hydrochloride' would be dual-labelled as 'lidocaine (lignocaine) hydrochloride'. Stakeholders asserted that this approach would assist with consumers' and healthcare professionals' transition to the new name.

This revised order of names has been included as the preferred approach in this RIS for most dual-labelled ingredients. As discussed earlier, adrenaline and noradrenaline products will be dual-labelled in the opposite order (adrenaline (epinephrine)) to harmonise with the UK example.

Stakeholders also nominated a number of additional ingredients for dual-labelling (for example sunscreens or ingredients where the first couple of letters have changed). Currently, sponsors can include additional information on labels to clarify the active ingredient (for example including a common name for a herbal preparation). TGA can also require that specific products include both names on their labels, case by case.

6.2.4 Communication and education

Many stakeholders (industry, healthcare professional and consumer) raised concerns about the risks of changing existing medicine names. Stakeholders noted the risks of medication errors if adequate education and resources were not provided to support the changes, particularly for substances of 'high clinical significance', anaesthetics or medicines used to treat chronic diseases.

Most stakeholders proposed a targeted communication and education strategy. Focussed communication activities were proposed for the following areas:

- Substances of high clinical significance
- Sunscreen active ingredients
- Common over-the-counter active ingredients
- Ingredients associated with allergies (both cause and treatment)
- Where an existing ingredient on the Ingredients Table has changed its meaning (i.e. 'carbidopa' to 'carbidopa monohydrate').

Stakeholders recommended that communication and education activities be implemented in close collaboration with government, industry and consumer and healthcare professional organisations. It was recommended that communication activities start before the ingredient name changes are implemented and continue throughout the transition period. See Section 8 – Implementation and review for more information on the proposed communication activities.

7. Conclusion

The main objective of the proposal is to provide clarity and consistency in naming (as far as possible) to support the quality use of medicines. The proposal also aims to minimise administrative costs for industry, thereby supporting the commercial viability of supplying medicines to Australian consumers.

This RIS outlines the following options to achieve these objectives:

- Option 1 proposes no change (status quo).
- Option 2 proposes to change 478 ingredient names to their harmonised nomenclature.
- Option 3 reduces the full proposal by applying status quo to:
  - 3a – Metal-containing ingredient names
  - 3b – Sunscreen active ingredient names
  - 3c – The spelling of some excipient names
  - 3d – Macrogol excipient names
- Option 4 proposes to further reduce name changes to only those where there is direct harmonisation with a reference, plus those considered of high clinical significance.
- Option 5 allows a voluntary approach to the proposed name changes (or a subset thereof).

The benefits of improved global harmonisation and contribution to the quality use of medicines for Australians will not be realised under Options 1 and 5. In considering the alternative mandatory adoption proposals (Options 2, 3 and 4), the most cost effective approach is sought to minimise implementation problems that may offset these benefits.

Option 3 is the preferred option. This option would increase the alignment of Australian ingredient names with widely accepted international terminology by harmonising a large proportion of the identified inconsistencies. At the same time, harmonisation will not be imposed when the regulatory costs would potentially outweigh the benefits. The net regulatory cost of this Option will be offset by other gains, such reduced risk of incorrect use of medicines and clarity for patients and healthcare providers. This option will also result in a small reduction in barriers to trade for individual companies, however it is not expected to have a noticeable effect on the market overall.

A four year transition period for these changes is proposed. This transition period would minimise most of the costs of the ingredient name changes as it fits well with business as usual label changes identified by industry during consultation.

To mitigate the risks to consumers, medicines with ingredients identified as of 'high clinical significance' would be dual-labelled with both the old and new name for an additional three years. Following this period, sponsors could then start using the new ingredient name as the sole name.

Due to the qualitative gains from harmonisation, this option is expected to result in an overall net benefit to consumers, healthcare professionals and industry once the name changes are embedded in Australian nomenclature.

8. Implementation and review

During the transition period, TGA will collaborate with product sponsors to update ingredient names in:

- Business Services Ingredients Table
- ARTG entries
- PIs/CMIs
- medicine labels.

8.1 Business Services Ingredients Table

TGA proposes to update the Ingredients Table with the new names at the beginning of the transition period. TGA will include in each entry any previously used names as synonyms for the new ingredient name. Therefore searches of the Ingredients Table using an old name will retrieve the new name entry.

Where the new ingredient name already exists in the Table, the old name will be hidden on the public interface. For example, both 'colecalciferol' and 'cholecalciferol' are current entries: 'C**h**olecalciferol' will be hidden and 'colecalciferol' will be the only visible entry for this substance. For those ingredients that do not have a new harmonised name already available, a new entry will be created. The old name will then be hidden. Once the Ingredients Table is updated, sponsors would only be able to use the new harmonised names for entering new products onto the ARTG.

TGA will also ensure that these name changes flow onto other TGA Business Services systems (listed medicine validation rules, the Prescription Medicines Electronic Lodgement facility [PREMIER] etc.).

For dual-labelled ingredients, the name change process will be the same as for other ingredient name changes. At the end of the dual-labelling period, TGA will change the dual-labelled ingredients[36] to their new name as the sole name. This will be done by changing the dual-labelled entry to its sole name in the Ingredients Table. Sponsors would be able to voluntarily change their ARTG entries to reflect the harmonised name as the sole name.

8.2 ARTG

TGA will update affected ARTG entries in collaboration with sponsors. TGA will write to individual sponsors to notify them of this activity and of the need to assess their products for any associated changes to labelling or supporting product information. This letter will also include a return TGA form to acknowledge their cooperation with the updates.

TGA will also notify affected sponsors when the dual-labelling period has expired. At this time, affected ARTG entries will be automatically updated to the sole new name. No fee is associated with this change.

[36] Excluding adrenaline and noradrenaline entries.

8.3 PI and CMI

If the PI or CMI specifies an ingredient name that has been harmonised, this documentation will need to be updated to reflect the new name. For variations to the ARTG requested under s. 9D of the Act—including 9D(1), 9D(2) and 9D(3)—approval of a change to the PI is made under s. 25AA(4).

No fees will be charged to change a PI and CMI, as long as the only change is that to the ingredient name for the purposes of this harmonisation activity. Sponsors could apply to change the ingredient name on PI/CMI documentation at the same time as they wish to make other changes to their product details using the usual variation processes. However, these combined applications would be subject to the usual TGA fees.

For dual-labelled ingredients, both the old and new name will need to be specified in the 'active ingredient' section of the PI/CMI, as well as any other section where the old name is included. At the end of the dual-labelling period, sponsors will be able to move to using the sole name on PIs and CMIs voluntarily.

8.4 Changes to legislative instruments

Several legislative instruments will be updated to reflect the new names, specifically:

- TGO No. 80 (Child-Resistant Packaging Requirements for Medicines) – e.g. 'frusemide' will change to 'furosemide'.
- Therapeutic Goods Regulations 1990, Schedule 2 and Schedule 4 – e.g. 'cholecalciferol' and 'alpha-tocopherol' will change to their new names.
- Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) – ingredients may change to their harmonised name or be included as synonyms in the index. Some of these changes have already been implemented through separate SUSMP processes.

The same regulatory requirements will continue to apply for these ingredients, regardless of which name is used in the legislative instrument.

8.5 Communication and education

A communication strategy will help raise awareness of the changes for healthcare professionals and consumers so that the correct medicine is prescribed and taken.

The UK underwent a similar ingredient name harmonisation process in 2003, at which time British Approved Names and names of ingredients in the BP were updated to reflect international naming policy. The following communication and education strategies were developed applying the lessons learnt from the UK process, as well as input from stakeholders during consultation.

In line with the *TGA external communication and education framework 2013-2015*[37], TGA will work closely with consumer and healthcare professional organisations to develop and disseminate information about the ingredient name changes. These organisations have existing resources and networks that extend beyond those currently available to TGA.

[37] TGA external communication and education framework <https://www.tga.gov.au/publication/tga-external-communication-and-education-framework>

8.5.1 Targeted communication

TGA will work with the National Prescribing Service (NPS MedicineWise) and other consumer and healthcare professional organisations to develop communication and education strategies with a focus on:

- specific areas of practice (general practitioners, nurses, pharmacists) and
- specific types of ingredients (substances of high clinical significance, anaesthetics, ingredients used in common over-the-counter products).

A range of communication materials will be developed through different media. These will include articles in trade magazines, targeted mail-outs to sponsors and healthcare professionals, information pamphlets that healthcare professionals can pass on to consumers, and presentations at professional seminars or conferences. TGA will also investigate opportunities for updating practitioner training materials (such as reference texts – the Australian Medicines Handbook).

TGA will also create a dedicated page on the TGA website that will be a central source of information on the changes and contain a copy of useful communication and education materials. All communication materials will provide links back to this central webpage. This webpage will also include a searchable database of old and new active ingredient names. Consumers, healthcare professionals, industry and government would be able to check whether an ingredient name was changed.

8.5.2 Updating dispensing and prescribing software

TGA will work closely with NeHTA to implement ingredient name changes on prescribing and dispensing software. NeHTA currently adapts their terminology used in dispensing software from existing ARTG entries and TGA provides regular ARTG updates to ensure that their terminology is current. NeHTA moderates these changes, which can then flow onto prescribing and dispensing software that use NeHTA terminology.

The PBS has adopted the NeHTA medicines terminology. Any ingredient name changes that are taken up by NeHTA systems will be reflected in the PBS systems.

8.6 Monitoring and review

During the transition period, TGA will monitor a subset of ingredient name changes in PIs/CMIs and labels. TGA will also monitor queries from consumers, healthcare professionals and industry about the ingredient name changes. Specific monitoring attention will be given to ingredients of high clinical significance (those that have been dual-labelled).

TGA will review the success of the harmonisation activity by measuring the uptake of ingredient name changes and the number and type of stakeholder queries. This review will occur:

- At the end of the four year transition period and
- At the end of the dual-labelling period.

Appendix A: Costings and assumptions

Option 1 - Baseline assumptions

Number of medicine products in Australia (as at January 2015):

- There are approximately 33,000 medicine entries on the ARTG (15,000 Prescription; 3,000 OTC; 12,000 Listed; and 3,000 Export Only).
- Low value turnover rates have been used to estimate how many ARTG entries are not associated with a product currently marketed in Australia. Approximately half of ARTG entries are reported to TGA as having a low value turn-over[38], with the following breakdown:
  - Prescription – 62%
  - OTC – 36%
  - Listed – 35%
- Some ARTG entries cover more than one medicine unit (e.g. different pack sizes). A multiplier[39] is applied to ARTG entries for each of the following types of medicines:
  - Prescription – 2.3 medicines per ARTG entry
  - OTC – 2.5 medicines per ARTG entry
  - Listed –1.0 medicines per ARTG entry
- Based on the above figures, there are 25,585 total medicine products marketed in Australia (12,889 Prescription; 4,895 OTC; and 7,800 Listed)
- For many medicines, there is more than one label associated with a product. For example, a medicine in a blister pack is assumed to be associated with 2 labels (the backing of the blister container and the outside carton). Based on an analysis of ARTG entries, a multiplier is applied to the number of medicine products to estimate the number of associated labels:
  - Prescription – 1.89 labels per medicine product
  - OTC – 1.85 labels per medicine product
  - Listed –1.05 labels per medicine product
  - An average multiplier of 1.60 is applied for some calculations.
- Over half (55%) of medicines are either a single product under a unique brand name or the first product in a range comprising the same brand name and active ingredient (usually differing in strength – e.g. 20mg vs. 40mg). The remaining 45% of products are the second and subsequent strengths in the brand with the same active ingredient.

[38] LVT Consultation: <https://www.tga.gov.au/consultation/consultation-review-low-value-turnover-exemption-scheme>
[39] Sourced from the 2104 survey of companies

Business-as-usual (BAU) variations to existing medicines:

- There is high variability between how often sponsors change an aspect of their product (e.g. update label, PI etc.). Some sponsors vary their ARTG entry regularly (even more than once a year), whereas other sponsors will not vary their products for several years. The majority of ARTG variation applications are for prescription products. For most listed medicines, instead of varying an ARTG entry, sponsors will cancel the product and replace it with a new ARTG entry.
- Based on a 2014 survey of companies, TGA assumes that existing products will change their labels as part of BAU, on average, every 3 years (i.e. half of all medicines will make an amendment to their label within 3 years).
- Total costs for minor changes to labels (e.g. changing an ingredient) as part of BAU vary depending on the type of medicine. However, as outlined in the 2014 consultation for medicine labelling reforms[40], the average cost for minor label changes is estimated as $2,180 per medicine.
- These minor label change costs include pre-production costs (such as label redesign and approval, artwork and proofing) and production costs (new printing plates for conventional printing processes, changes to the digital printing process). The costs also cover any potential changes to the PI/CMI.
- A minor label change is defined as a small change to the phrasing of text on a label that does not necessitate a change to, or rearrangement of, other label graphics.

Costs associated with a lack of harmonisation

- Based on similarities between products registered in Australia versus the US and European Union, 75% of affected products are marketed overseas as well as in Australia by the same company.
- There is a time-cost imposed on sponsors associated with preparing advertising/marketing materials using unharmonised ingredient names. Due to seasonal marketing, most advertising materials are assumed to be updated yearly. Many international companies are able to use marketing material from overseas. The cost of changing this ingredient name on international marketing material is estimated at 2 hours per product line[41] per year, at an hourly wage of $65.45 per hour[42].
- There is a time-cost for sponsors resulting from a lack of harmonisation or inconsistencies and ambiguity within the TGA Business Services Ingredient Tables. These costs include time spent researching and selecting appropriate ingredient names, complexity during internal safety or technical complaints reporting, and/or responding to TGA requests for further information if an ingredient within a product application does not match the Australian Approved Name. This cost is estimated at 3 hours per year per affected sponsor, at an hourly wage rate of $65.45 per hour.
- The indirect costs of imposing a barrier to international trade for Australian businesses through a lack of harmonisation could not be calculated.

[40] <https://www.tga.gov.au/consultation/consultation-medicine-labelling>
[41] Only active ingredients are included in advertising material.
[42] OBPR data, includes on-cost multiplier 1.75

Option 2 – Mandatory adoption – the full proposal

Option 2 proposes to change the names of 478 ingredients.

This option would affect **18,758 ARTG medicine entries** (approximately 54% prescription, 12% OTC, 35% Listed) and **1,029 sponsors**. The same baseline assumptions for BAU have been used as outlined under Option 1.

Regulatory cost assumptions

Number of medicine products affected and cost of changes

- Based on the baseline assumptions, 16,431 medicine products currently marketed in Australia will be affected, with the following breakdown:
  - Prescription: 8,698 products
  - OTC: 3,526 products
  - Listed: 4,208 products
- Labels will be affected if the change is to an active ingredient (25% of the changes).
- Based on the BAU costs outlined in Option 1, the following label pre-production and production costs are assumed (total $14.89M):
  - Prescription: $8.95M
  - OTC: $3.54M
  - Listed: $2.41M
- Most of the ingredient name changes involve the change of one letter, addition/removal of a hydration state, removal of hyphen or a change in word order. Products affected by dual labelling will require additional information on the label (as an ingredient needs to be identified with both old and new names), however this still fits the definition of a minor change. Medicines associated with 194 ARTG entries will require dual labelling at an estimated cost of $1.96M.
- Where an ingredient is within a Proprietary Ingredient, there would be no effect on label or other documentation and no regulatory burden has been estimated. Approximately 34% of the proposed changes are to ingredients within Proprietary Ingredients.
- The above costs of updating labels include costs associated with updating PI/CMI documentation. Some PIs will only need to update an excipient name without updating a label – estimated at 15% of prescription only product lines. Production costs for a changed PI document are estimated at $147. The PI/CMI updating cost is estimated at $0.10M.
- The one-off labour burden for businesses that need to make the required changes on internal documents, labels and PI/CMI documents would be approximately 4 hours per product line, at a labour rate of $65.45 per hour. This includes 2 hours to assess what changes need to be made to products and 2 hours to make any changes (update names, QA, complete and return template TGA letter as part of the application to vary the ARTG).
- The labour involved in the second and subsequent products in a product line would equate to an extra 2 hours per additional product. The total labour cost for the changes is estimated as $3.33M.

- The total one-off cost for ingredient changes under Option 2 (prior to discounts due to BAU and transition timeframes) is estimated as $18.33M.

Benefits of harmonisation

- In an attempt to provide an estimate of the benefits of harmonisation, TGA assumes that each individual ingredient name change will result in an equal amount of benefit to each sponsor.
- According to the costs identified in Option 1, harmonisation of active ingredient names would provide an ongoing saving to sponsors. This arises from the reduction of costs associated with developing and varying advertising and marketing materials and supporting documentation between Australia and other markets and is estimated at $353,210 per annum over 10 years.
- Harmonisation and resolution of Ingredients Tables inconsistencies will also save industry time spent researching and selecting appropriate ingredient names, complexity during internal safety or technical complaints reporting, and/or responding to TGA requests for further information if an ingredient within a product application does not match the Australian Approved Name. This saving is estimated at $202,044 per annum over 10 years.
- The total benefit from Option 2 per annum over 10 years is estimated at $0.56M.

Transition options

Transition Option (i): proposes a **three year** transition period for changing ingredient names. Substances identified as being of 'high clinical significance' would be required to be dual-labelled (with old and new names) for an additional three years. Those medicines with dual-labelling could voluntarily move to use of the new ingredient name as the sole name after this period.

- Approximately 50 per cent of affected products would have changed within the three year period as part of BAU (as per a normal skewed right distribution curve).
- The remaining 50 per cent of products would need to bring forward any planned changes to labels and other documentation to avoid having to pay twice for changes (once for the regulatory changes, once for the business need). A 6 per cent discount rate (per annum) has been applied to products that would need to change labels earlier than would be required as part of ordinary business:
  - Those that would normally change in a four year cycle, but are being forced to change 1 year earlier (25 per cent). A 6% rate has been applied to the full cost of changes for these products as part of BAU.
  - Those that would normally change in a five year cycle, but are being forced to change 2 years earlier (15 per cent). A 12% rate has been applied to the full cost of changes for these products as part of BAU.
  - Those that would never normally change (10 per cent). The full cost of the ingredient name changes would apply for products in this category.
- The total cost for Option 2(i), including the benefits outlined above, is **$0.91M per annum over 10 years.**

Transition Option (ii): proposes a **four year** transition period for changing ingredient names. Substances identified as being of 'high clinical significance' would be required to be dual-labelled (with old and new names) for an additional three years. Those medicines with dual-labelling could voluntarily move to use of the new ingredient name as the sole name after this period.

- Approximately 75 per cent of affected products would have changed within the four year period as part of BAU (as per a normal skewed right distribution curve).
- The remaining 25 per cent of products would need to bring forward any planned changes to labels and other documentation to avoid having to pay twice for changes (once for the regulatory changes, once for the business need). A 6 per cent discount rate (per annum) has been applied to products that would need to change labels earlier than would be required as part of ordinary business:
  - Those that would normally change in a five year cycle, but are being forced to change 1 year earlier (15 per cent). A 6% rate has been applied to the full cost of changes for these products as part of BAU.
  - Those that would never normally change (10 per cent). The full cost of the ingredient name changes would apply for products in this category.
- The total cost for Option 2(ii), including the benefits outlined above, is **$0.23M per annum over 10 years.**

Option 3 – Mandatory adoption – a reduced proposal (PREFERED OPTION)

Under this option, 336 ingredient names will change. This option would affect **17,886 ARTG entries** (55% prescription, 11% OTC, 34% Listed) and **972 sponsors**.

The same baseline and transition assumptions have been used for Option 3 as for the previous options.

Regulatory cost assumptions

Number of medicine products affected and cost of changes

- Based on the baseline assumptions, Option 3 will affect 15,636 medicine products currently marketed in Australia, with the following breakdown:
  - Prescription: 8,496 products
  - OTC: 3,228 products
  - Listed: 3,917 products
- Labels will be affected if the change is to an active ingredient (22% of the changes).
- Based on the BAU costs outlined in Option 1, the following label pre-production and production costs are assumed (total $12.82M):
  - Prescription: $7.88M
  - OTC: $2.93M
  - Listed: $2.02M
- Where an ingredient is within a Proprietary Ingredient, there would be no effect on label or other documentation and no regulatory burden has been estimated. Approximately 18% of the proposed changes are to ingredients within Proprietary Ingredients.
- The PI/CMI updating cost is estimated at $0.10M.

- The one-off labour burden for businesses that need to make the required changes on internal documents, labels and PI/CMI documents would be approximately 4 hours per product line, at a labour rate of $65.45 per hour. This includes 2 hours to assess what changes need to be made to products and 2 hours to make any changes (update names, QA, complete and return template TGA letter as part of the application to vary the ARTG).
- The labour involved in the second and subsequent products in a product line would equate to an extra 2 hours per additional product. The total labour cost for the changes is estimated as $3.17M.
- The total one-off cost for ingredient changes under Option 3 (prior to discounts due to BAU and transition timeframes) is estimated as $16.09M.

Benefits of harmonisation

- In an attempt to provide an estimate of the benefits of harmonisation, TGA assumes that each individual ingredient name change will result in an equal amount of benefit to each sponsor.
- According to the costs identified in Option 1, harmonisation of active ingredient names would provide an ongoing saving to sponsors. This arises from the reduction of costs associated with developing and varying advertising and marketing materials and supporting documentation between Australia and other markets and is estimated at $303,160 per annum over 10 years.
- Harmonisation and resolution of Ingredients Database inconsistencies will also save industry time spent researching and selecting appropriate ingredient names, complexity during internal safety or technical complaints reporting, and/or responding to TGA requests for further information if an ingredient within a product application does not match the Australian Approved Name. This saving is estimated at $190,852 per annum over 10 years.
- The total benefit from Option 3 per annum over 10 years is estimated at $0.49M.

Transition options

Transition Option (i): proposes a **three year** transition period for changing ingredient names. Substances identified as being of 'high clinical significance' would be required to be dual-labelled (with old and new names) for an additional three years. Those medicines with dual-labelling could voluntarily move to use of the new ingredient name as the sole name after this period.

- Approximately 50 per cent of affected products would have changed within the three year period as part of BAU (as per a normal skewed right distribution curve).
- The remaining 50 per cent of products would need to bring forward any planned changes to labels and other documentation to avoid having to pay twice for changes (once for the regulatory changes, once for the business need). A 6 per cent discount rate (per annum) has been applied to products that would need to change labels earlier than would be required as part of ordinary business:
  - Those that would normally change in a four year cycle, but are being forced to change 1 year earlier (25 per cent). A 6% rate has been applied to the full cost of changes for these products as part of BAU.
  - Those that would normally change in a five year cycle, but are being forced to change 2 years earlier (15 per cent). A 12% rate has been applied to the full cost of changes for these products as part of BAU.
  - Those that would never normally change (10 per cent). The full cost of the ingredient name changes would apply for products in this category.

- The total cost for Option 3(i), including the benefits outlined above, is **$0.73M per annum over 10 years.**

Transition Option (ii): proposes a **four year** transition period for changing ingredient names. Substances identified as being of 'high clinical significance' would be required to be dual-labelled (with old and new names) for an additional three years. Those medicines with dual-labelling could voluntarily move to use of the new ingredient name as the sole name after this period.

- Approximately 75 per cent of affected products would have changed within the four year period as part of BAU (as per a normal skewed right distribution curve).
- The remaining 25 per cent of products would need to bring forward any planned changes to labels and other documentation to avoid having to pay twice for changes (once for the regulatory changes, once for the business need). A 6 per cent discount rate (per annum) has been applied to products that would need to change labels earlier than would be required as part of ordinary business:
  - Those that would normally change in a five year cycle, but are being forced to change 1 year earlier (15 per cent). A 6% rate has been applied to the full cost of changes for these products as part of BAU.
  - Those that would never normally change (10 per cent). The full cost of the ingredient name changes would apply for products in this category.
- The total cost for Option 3(ii), including the benefits outlined above, is **$0.13M per annum over 10 years.**

Option 4 – Mandatory adoption – Direct harmonisation of INN/reference and substances of high clinical significance

Under this option, 160 ingredient names will change. This option would affect **6,478 ARTG entries** (47% prescription, 13% OTC, 29% Listed) and **350 sponsors**.

The same baseline and transition assumptions have been used for Option 4 as for the previous options.

Regulatory cost assumptions

Number of medicine products affected and cost of changes

- Based on the baseline assumptions, Option 4 will affect 5,142 medicine products currently marketed in Australia, with the following breakdown:
  - Prescription: 2,599 products
  - OTC: 1,330 products
  - Listed: 1,213 products
- Labels will be affected if the change is to an active ingredient (50% of the changes).
- Based on the BAU costs outlined in Option 1, the following label pre-production and production costs are assumed (total $9.44M):
  - Prescription: $5.37M
  - OTC: $2.68M

  - Listed: $1.39M

- The PI/CMI updating cost is estimated at $0.01M.
- The one-off labour burden for businesses that need to make the required changes on internal documents, labels and PI/CMI documents would be approximately 4 hours per product line, at a labour rate of $65.45 per hour. This includes 2 hours to assess what changes need to be made to products and 2 hours to make any changes (update names, QA, complete and return template TGA letter as part of the application to vary the ARTG).
- The labour involved in the second and subsequent products in a product line would equate to an extra 2 hours per additional product. The total labour cost for the changes is estimated as $1.04M.
- The total one-off cost for ingredient changes under Option 4 (prior to discounts due to BAU and transition timeframes) is estimated as $10.50M.

Benefits of harmonisation

- In an attempt to provide an estimate of the benefits of harmonisation, TGA assumes that each individual ingredient name change will result in an equal amount of benefit to each sponsor.
- According to the costs identified in Option 1, harmonisation of active ingredient names would provide an ongoing saving to sponsors. This arises from the reduction of costs associated with developing and varying advertising and marketing materials and supporting documentation between Australia and other markets and is estimated at $221,899 per annum over 10 years.
- Harmonisation and resolution of Ingredients Database inconsistencies will also save industry time spent researching and selecting appropriate ingredient names, complexity during internal safety or technical complaints reporting, and/or responding to TGA requests for further information if an ingredient within a product application does not match the Australian Approved Name. This saving is estimated at $68,723 per annum over 10 years.
- The total benefit from Option 4 per annum over 10 years is estimated at $0.29M.

Transition options

Transition Option (i): proposes a **three year** transition period for changing ingredient names. Substances identified as being of 'high clinical significance' would be required to be dual-labelled (with old and new names) for an additional three years. Those medicines with dual-labelling could voluntarily move to use of the new ingredient name as the sole name after this period.

- Approximately 50 per cent of affected products would have changed within the three year period as part of BAU (as per a normal skewed right distribution curve).
- The remaining 50 per cent of products would need to bring forward any planned changes to labels and other documentation to avoid having to pay twice for changes (once for the regulatory changes, once for the business need). A 6 per cent discount rate (per annum) has been applied to products that would need to change labels earlier than would be required as part of ordinary business:
  - Those that would normally change in a four year cycle, but are being forced to change 1 year earlier (25 per cent). A 6% rate has been applied to the full cost of changes for these products as part of BAU.

- Those that would normally change in a five year cycle, but are being forced to change 2 years earlier (15 per cent). A 12% rate has been applied to the full cost of changes for these products as part of BAU.
- Those that would never normally change (10 per cent). The full cost of the ingredient name changes would apply for products in this category.

· The total cost for Option 4(i), including the benefits outlined above, is **$0.51M per annum over 10 years.**

Transition Option (ii): proposes a **four year** transition period for changing ingredient names. Substances identified as being of 'high clinical significance' would be required to be dual-labelled (with old and new names) for an additional three years. Those medicines with dual-labelling could voluntarily move to use of the new ingredient name as the sole name after this period.

· Approximately 75 per cent of affected products would have changed within the four year period as part of BAU (as per a normal skewed right distribution curve).

· The remaining 25 per cent of products would need to bring forward any planned changes to labels and other documentation to avoid having to pay twice for changes (once for the regulatory changes, once for the business need). A 6 per cent discount rate (per annum) has been applied to products that would need to change labels earlier than would be required as part of ordinary business:

- Those that would normally change in a five year cycle, but are being forced to change 1 year earlier (15 per cent). A 6 per cent rate has been applied to the full cost of changes for these products as part of BAU.
- Those that would never normally change (10 per cent). The full cost of the ingredient name changes would apply for products in this category.

· The total cost for Option 4(ii), including the benefits outlined above, is **$0.12M per annum over 10 years.**

Appendix B: Ingredient name changes (preferred option)

The following ingredient names are proposed to change under the preferred option (Option 3).

Table B.1. Ingredient name changes under the preferred option (Option 3)

ID	Ingredient name	Ref	New ingredient name	New ref	Dual labelling?
53999	2-hydroxymethylfuran	MI	furfuryl alcohol	MI	
81918	3-phenyl propyl alcohol	PFC	phenylpropanol	USAN	
51951	6-acetyl-1,1,3,4,4,6-hexamethyl tetrahydronaphthalene	PFC	7-acetyl-1,1,3,4,4,6-hexamethyl tetrahydronaphthalene	PFC	
54012	8-hydroxyquinoline	MI	oxyquinoline	USAN	
51965	Acriflavine	MAR	acriflavinium chloride	INN	
58903	Actinomycin D	BAN	dactinomycin	INN	YES
51982	Adrenaline	BP	adrenaline (epinephrine)	BP	
51983	Adrenaline acid tartrate	BPM	adrenaline (epinephrine) acid tartrate	BPM	
100580	Adrenaline acid tartrate (epinephrine acid tartrate)	BPM	adrenaline (epinephrine) acid tartrate	BPM	
51985	Adrenaline hydrochloride	BPM	adrenaline (epinephrine) hydrochloride	BPM	
100581	Adrenaline hydrochloride (epinephrine hydrochloride)	BPM	adrenaline (epinephrine) hydrochloride	BPM	
93569	Alizarin cyanine green F	MI	acid green 25	CI	
52016	Allylamyl glycollate	CAS	allyl amyl glycolate	TGA	
96313	Alpha tocopherol	BP	dl-alpha-tocopherol	USPM	
96314	Alpha tocopherol acetate	BP	dl-alpha-tocopheryl acetate	USPM	

ID	Ingredient name	Ref	New ingredient name	New ref	Dual labelling?
52047	Alum	BP	alum dodecahydrate	BPM	
52059	Aluminium hydroxide	MI	aluminium hydroxide hydrate	BPM	
57910	Aluminium hydroxide - dried	BP	aluminium hydroxide	BP	
52063	Aluminium nitrate	MI	aluminium nitrate nonahydrate	BPAPM	
88051	Aluminium oxide anhydrous	MI	aluminium oxide	MI	
71128	Aluminium sulfate	BP	aluminium sulfate hydrate	BP	
52086	Amethocaine hydrochloride	BP	tetracaine hydrochloride	BP	YES
52090	Amiloride hydrochloride	BP	amiloride hydrochloride dihydrate	BPM	
52091	Aminacrine hydrochloride	BAN	aminoacridine hydrochloride	BAN	
56667	Amlodipine besylate	BAN	amlodipine besilate	BP	
52122	Ammonium hydroxide	MAR	strong ammonia solution	BP	
52122	Ammonium hydroxide	MAR	dilute ammonia solution	BP	
56480	Amoxycillin	BP	amoxicillin	INN	
60720	Amoxycillin sodium	BP	amoxicillin sodium	BP	
52133	Amoxycillin trihydrate	BP	amoxicillin trihydrate	BP	
52137	Amphotericin	BP	amphotericin B	INN	YES
52166	Amylobarbitone sodium	BP	amobarbital sodium	BP	YES
52206	Antimony potassium tartrate	USP	antimony potassium tartrate trihydrate	USPM	
95337	Apomorphine hydrochloride	BP	apomorphine hydrochloride hemihydrate	BPM	

ID	Ingredient name	Ref	New ingredient name	New ref	Dual labelling?
52235	Atracurium besylate	BAN	atracurium besilate	BP	
70757	Atropine sulfate	BP	atropine sulfate monohydrate	BPM	
96610	Bacillus Calmette and Guerin	BP	Mycobacterium bovis (Bacillus Calmette and Guerin (BCG) strain)	BP	YES
52278	Beclomethasone Dipropionate	BP	beclometasone dipropionate	BP	
94769	Bee	AIN	honey bee	HPUS	
103481	Bee venom	HPUS	honey bee venom	AIN	
52304	Benzhexol hydrochloride	BP	trihexyphenidyl hydrochloride	BP	YES
52309	Benzodihydropyrone	FCC	dihydrocoumarin	FCC	
52320	Benztropine mesylate	BP	benzatropine mesilate	BP	
52350	Berberine hydrochloride	MAR	berberine chloride	BPAP	
52414	Bretylium tosylate	BAN	bretylium tosilate	BP	
52427	Bromocriptine mesylate	BP	bromocriptine mesilate	BP	
52448	Bupivacaine hydrochloride	BP	bupivacaine hydrochloride monohydrate	BPM	
101754	Bupivacaine hydrochloride anhydrous	BP	bupivacaine hydrochloride	BP	
52467	Butoxyethyl nicotinate	MAR	nicoboxil	INN	
52473	Butyl aminobenzoate	USAN	butamben	USP	
93476	C12-15 alkyl benzoate	ICID	alkyl (C12-15) benzoate	USP	
52528	Calcium chloride	BP	Calcium chloride dihydrate	BP	

ID	Ingredient name	Ref	New ingredient name	New ref	Dual labelling?
97719	Calcium citrate hydrate	MI	calcium citrate tetrahydrate	USANM	
52538	Calcium gluconate	BP	calcium gluconate monohydrate	BPM	
52543	Calcium hydrogen phosphate	BP	calcium hydrogen phosphate dihydrate	BPM	
95202	Calcium hydrogen phosphate anhydrous	BP	calcium hydrogen phosphate	BPM	
100565	Calcium lactate anhydrous	BP	calcium lactate	BPM	
63405	Calcium sulfate	BPAP	calcium sulfate dihydrate	BP	
92089	Calcium sulfate anhydrous	USP	calcium sulfate	USP	
91543	Caldiamide sodium	BAN	caldiamide sodium hydrate	BANM	
60531	Caprylic/capric triglyceride	ICID	medium chain triglycerides	BP	
52614	Carbidopa	BP	carbidopa monohydrate	BPM	
87613	Carbidopa anhydrous	BP	carbidopa	INN	
52685	Cellacephate	BP	cellacefate	INN	
52689	Cephalexin	BP	cefalexin monohydrate	BP	
100859	Cephalexin anhydrous	BP	cefalexin	BP	
52691	Cephalothin sodium	BP	cefalotin sodium	BP	
81269	Cephamandole	BAN	cefamandole	INN	
71817	Cephazolin	BAN	cefazolin	INN	
52695	Cephazolin sodium	BAN	cefazolin sodium	BP	
89428	Cetyl dimethicone	ICID	cetyl dimeticone	ICIDM	

ID	Ingredient name	Ref	New ingredient name	New ref	Dual labelling?
99554	Chitosan	ICID	poliglusam	INN	
52739	Chlorbutol	BP	chlorobutanol hemihydrate	BPM	
100585	Chlorphenamine maleate (Chlorpheniramine maleate)	BP	chlorphenamine maleate	BP	
52779	Chlorpheniramine maleate	BP	chlorphenamine maleate	BP	
52793	Chlorthalidone	BP	chlortalidone	INN	
52796	Cholecalciferol	BP	colecalciferol	INN	
52798	Cholestyramine	BAN	colestyramine	INN	
94798	Chromic chloride	USP	chromic chloride hexahydrate	USPM	
95567	cis-3-Hexenyl caproate	PFC	cis-3-hexenyl hexanoate	PFCM	
96377	Cisatracurium besylate	BAN	cisatracurium besilate	INN	
97439	Citric acid - anhydrous	BP	citric acid	BPM	
52917	Clomiphene citrate	BP	clomifene citrate	BP	
73497	Coco-caprylate/caprate	ICID	coco-octanoate/decanoate	ICIDM	
52959	Codeine phosphate	BP	codeine phosphate hemihydrate	BP	
52966	Colaspase	BAN	asparaginase	USAN	YES
93010	Co-methylcobalamin	MI	mecobalamin	INN	YES
94811	Crystal violet CI42555	MAR	methylrosanilinium chloride	INN	YES
94806	Cupric sulfate anhydrous	MI	cupric sulfate	MIM	
94518	Cyanocobalamin(57Co)	BP	cyanocobalamin (57Co)	INN	

ID	Ingredient name	Ref	New ingredient name	New ref	Dual labelling?
53054	Cyclophosphamide	BP	cyclophosphamide monohydrate	INNM	
53057	Cyclosporin	BAN	ciclosporin	INN	
53063	Cyproheptadine hydrochloride	BP	cyproheptadine hydrochloride sesquihydrate	BPM	
97278	Cysteamine bitartrate	BAN	mercaptamine bitartrate	BAN	YES
53073	Dantrolene sodium	BAN	dantrolene sodium hemiheptahydrate	INNM	
105603	DEA-C8-18 perfluoroalkylethyl phosphate	ICID	diolamine C8-18 perfluoroalkylethyl phosphate	ICIDM	
70697	DEA-cetyl phosphate	ICID	diolamine cetyl phosphate	ICIDM	
63559	Decan-1-ol	BPAP	decyl alcohol	BPAP	
97447	Delavirdine mesylate	USAN	delavirdine mesilate	USAN	
53110	Desferrioxamine mesylate	BP	desferrioxamine mesilate	BP	
81377	Dexamphetamine sulfate	BP	dexamfetamine sulfate	BPM	
53142	Dextromethorphan hydrobromide	BP	dextromethorphan hydrobromide monohydrate	BPM	
53146	Dextropropoxyphene napsylate	BP	dextropropoxyphene napsilate monohydrate	BP	
68290	Diazolidinylurea	ICID	diazolidinyl urea	ICID	
91312	Diclofenac diethylammonium	BAN	diclofenac diethylamine	BP	
96353	Diethyl toluamide	ICID	diethyltoluamide	INN	
53233	Dihydroergotamine mesylate	BP	dihydroergotamine mesilate	BP	

ID	Ingredient name	Ref	New ingredient name	New ref	Dual labelling?
53248	Di-iodohydroxyquinoline	BAN	diiodohydroxyquinoline	INN	
53250	Di-isopropanolamine	USP	diisopropanolamine	USP	
104168	Dimeglumine gadobenate	BP	gadobenate dimeglumine	BPM	
72289	Dimeglumine gadopentetate	USAN	gadopentetate dimeglumine	USPM	
85525	Dimethicone 10	BP	dimeticone 10	BPM	
91502	Dimethicone 100	BP	dimeticone 100	BPM	
58347	Dimethicone 1000	BP	dimeticone 1000	BPM	
96967	Dimethicone 1510	BP	dimeticone 1510	BPM	
96336	Dimethicone 20	BP	dimeticone 20	BPM	
73472	Dimethicone 200	BP	dimeticone 200	BPM	
104415	Dimethicone 30	BP	dimeticone 30	BPM	
64435	Dimethicone 350	BP	dimeticone 350	BPM	
84714	Dimethicone 450	BP	dimeticone 450	BPM	
98939	Dimethicone 5	BP	dimeticone 5	BPM	
80998	Dimethicone 50	BP	dimeticone 50	BPM	
66689	Dimethicone copolyol	ICID	dimeticone copolyol	ICIDM	
94065	Dimethicone copolyol phosphate	ICID	dimeticone copolyol phosphate	ICIDM	
66554	Dimethiconol	ICID	dimeticonol	ICIDM	
101709	Dimethiconol stearate	ICID	dimeticonol stearate	ICIDM	

ID	Ingredient name	Ref	New ingredient name	New ref	Dual labelling?
95372	Di-N propyl isocinchomeronate	CAS	di-n-propyl isocinchomeronate	CAS	
81428	Diphemanil methylsulfate	BAN	diphemanil metilsulfate	INN	
53315	Diphenyl ether	MI	diphenyl oxide	MI	
102486	Disodium dimethicone copolyol sulfosuccinate	ICID	disodium dimeticone copolyol sulfosuccinate	ICIDM	
53329	Disodium etidronate	BAN	etidronate disodium	BP	
68222	Disodium pamidronate	BAN	pamidronate disodium	BPM	
102195	dl-alpha tocopherol phosphate disodium	CAS	dl-alpha-tocopheryl phosphate disodium	CAS	
93271	dl-alpha tocopheryl acetate	BP	dl-alpha-tocopheryl acetate	USPM	
59836	DMDM Hydantoin	ICID	dimethylol dimethyl hydantoin	ICIDM	
97007	Dolasetron mesylate	BAN	dolasetron mesilate monohydrate	BANM	
1000587	Dosulepin hydrochloride (Dothiepin hydrochloride)	BP	dosulepin hydrochloride	BP	YES
53367	Dothiepin hydrochloride	BP	dosulepin hydrochloride	BP	YES
56553	Doxazosin mesylate	BAN	doxazosin mesilate	BP	
53373	Doxycycline hydrochloride	BP	doxycycline hyclate	BP	YES
87433	Edetate dipotassium	MI	edetate dipotassium dihydrate	USANM	
96966	Eformoterol	BAN	formoterol	INN	YES
97220	Eformoterol fumarate	BAN	formoterol fumarate	BPM	YES
97221	Eformoterol fumarate dihydrate	BAN	formoterol fumarate dihydrate	BP	YES
91756	Eosine	MAR	acid red 87	MAR	

ID	Ingredient name	Ref	New ingredient name	New ref	Dual labelling?
97830	Eprosartan mesylate	BAN	eprosartan mesilate	BAN	
53458	Ethacrynic acid	BP	etacrynic acid	INN	
53463	Ethanolamine	BP	monoethanolamine	INN	
81464	Ether - solvent	BP	ether	BP	
53471	Ethinyloestradiol	BP	ethinylestradiol	INN	
100719	Ethyl oenantate	MI	ethyl enantate	INNM	
53547	Ethyl oenanthate	MI	ethyl enantate	INNM	
53515	Ethylene glycol monostearate	MAR	ethylene glycol monopalmitostearate	BP	
93304	Ethylene/VA copolymer	ICID	ethylene/vinyl acetate copolymer	ICIDM	
53539	Ethylmorphine hydrochloride	BP	ethylmorphine hydrochloride dihydrate	BPM	
53565	Ethynodiol diacetate	BP	etynodiol diacetate	BP	
94818	Ferric chloride anhydrous	MAR	ferric chloride	MIM	
92469	Ferric nitrate	BPAP	ferric nitrate nonahydrate	BPAPM	
53633	Ferrous lactate	MAR	ferrous lactate trihydrate	MARM	
53635	Ferrous phosphate	MAR	ferrous phosphate octahydrate	MIM	
69280	Ferrous sulfate	BP	ferrous sulfate heptahydrate	BPM	
68856	Ferrous sulfate - dried	BP	ferrous sulfate	BPM	
59987	Flucloxacillin magnesium	BP	flucloxacillin magnesium octahydrate	BP	
53651	Flucloxacillin sodium	BP	flucloxacillin sodium monohydrate	BPM	

ID	Ingredient name	Ref	New ingredient name	New ref	Dual labelling?
53662	Flumethasone pivalate	BAN	flumetasone pivalate	BP	
81511	Flupenthixol decanoate	BAN	flupentixol decanoate	BP	
90838	Flurbiprofen sodium	USP	flurbiprofen sodium dihydrate	USPM	
53730	Frusemide	BP	furosemide	INN	YES
102321	Frusemide sodium	BP	furosemide sodium	BP	YES
100588	Furosemide (Frusemide)	BP	furosemide	INN	YES
53743	Fusidic acid	BP	fusidic acid hemihydrate	BPM	
94521	Gallium(67Ga) citrate	BP	gallium (67Ga) citrate	INN	
101812	Glucosamine sulfate-potassium chloride complex	TGA	glucosamine sulfate potassium chloride	USP	
101813	Glucosamine sulfate-sodium chloride complex	TGA	glucosamine sulfate sodium chloride	USP	
53790	Glucose	BP	glucose monohydrate	BPM	
58055	Glucose - anhydrous	BP	glucose	BPM	
53795	Glutaraldehyde	BP	glutaral	INN	
94891	Glycerol triacetate	BPAP	triacetin	INN	
53805	Glyceryl mono-oleate	MAR	glyceryl monooleate	USP	
53813	Glycol salicylate	MAR	hydroxyethyl salicylate	BP	
61974	Glycol stearate	ICID	ethylene glycol monopalmitostearate	ICID	
73454	Glycollic acid	MI	glycolic acid	MI	
53814	Glycopyrrolate	USP	glycopyrronium bromide	INN	YES

ID	Ingredient name	Ref	New ingredient name	New ref	Dual labelling?
85484	Glycyrrhetinic acid	ICID	enoxolone	INN	
53839	Guaiphenesin	BP	guaifenesin	INN	
93306	Haematoporphyrin	MAR	hematoporphyrin	MI	
95160	Haematoporphyrin dihydrochloride	MAR	hematoporphyrin dihydrochloride	MIM	
53856	Halethazole	BAN	haletazole	INN	
93288	Heparinoid	MAR	heparinoids	MAR	
72588	Hercolyn	PFC	methyl hydrogenated rosinate	PFC	
53892	Hexachlorophane	BP	hexachlorophene	INN	
53899	Hexamidine isethionate	MAR	hexamidine isetionate	BP	
53903	Hexamine hippurate	BAN	methenamine hippurate	INN	
53994	Hydroxyethylcellulose	BP	hyetellose	INN	
53995	Hydroxyethylmethylcellulose	BP	hymetellose	INN	
81585	Hydroxyethylrutosides	MAR	oxerutins	BAN	
98418	Hydroxypropyl beta cyclodextrin	USP	hydroxypropylbetadex	BP	
67610	Hydroxypropylcellulose	BP	hyprolose	INN	
81590	Hydroxyquinoline sulfate	MAR	oxyquinoline sulfate	USP	
54017	Hydroxyurea	BP	hydroxycarbamide	INN	YES
75213	Hyoscyamine sulfate	BP	hyoscyamine sulfate dihydrate	BPM	
102968	Imatinib mesylate	INN M	imatinib mesilate	INNM	

ID	Ingredient name	Ref	New ingredient name	New ref	Dual labelling?
93243	Indium(111In) chloride	USAN	indium (111In) chloride	USPM	
94522	Indium(111In) hydroxyquinoline	BP	indium (111In) hydroxyquinoline	USPM	
94523	Indium(111In) pentetate	BP	indium (111In) pentetate	BPM	
54059	Indomethacin	BP	indometacin	INN	
56468	Indomethacin sodium	USP	indometacin sodium trihydrate	INNM	
54067	Insulin - human	BP	insulin	BP	
104169	Iobenguane(123I) sulfate	USAN	iobenguane (123I) sulfate	USANM	
94069	Iodobenzylguanidine(131I) sulfate	USAN	iobenguane (131I) sulfate	USAN	
96978	Ipratropium bromide	BP	ipratropium bromide monohydrate	INNM	
98828	Ipratropium bromide anhydrous	BP	ipratropium bromide	INN	
97484	Irinotecan hydrochloride	USAN	irinotecan hydrochloride trihydrate	USP	
54148	Isoascorbic acid	MI	erythorbic acid	USP	
89431	iso-Cyclocitral	PFC	isocyclocitral	PFC	
54200	Isopropyl adipate	PFC	diisopropyl adipate	MAR	
95457	Isopropyl hydroxybenzoate	ICID	isopropyl 4-hydroxybenzoate	ICID	
89823	Lactobacillus kefir	IJFM	Lactobacillus kefiri	LPSN	
54252	Lactose	BP	lactose monohydrate	BPM	
79271	Lactose anhydrous	BP	lactose	BPM	

ID	Ingredient name	Ref	New ingredient name	New ref	Dual labelling?
105549	Lapatinib ditosylate monohydrate	USAN	lapatinib ditosilate monohydrate	USANM	
94229	Laureth-9	ICID	lauromacrogol 400	INN	
61067	Lauryl diethanolamide	CAS	lauramide DEA	CAS	
89539	Laurylmethicone copolyol	ICID	laurylmeticone copolyol	ICIDM	
54310	Lignocaine	BP	lidocaine	INN	YES
54311	Lignocaine hydrochloride	BP	lidocaine hydrochloride monohydrate	BPM	YES
93311	Lignocaine hydrochloride anhydrous	BP	lidocaine hydrochloride	BP	YES
94548	Lime	USP	calcium oxide	USP	
54327	Lincomycin hydrochloride	BP	lincomycin hydrochloride monohydrate	BPM	
54382	Magnesium acetate	BP	magnesium acetate tetrahydrate	BP	
54386	Magnesium aspartate	MAR	magnesium aspartate tetrahydrate	MARM	
105258	Magnesium aspartate anhydrous	MAR	magnesium aspartate	BPM	
54388	Magnesium carbonate	USP	magnesium carbonate hydrate	USPM	
57943	Magnesium carbonate - heavy	BP	magnesium carbonate hydrate	USPM	
58330	Magnesium carbonate - light	BP	magnesium carbonate hydrate	USPM	
54389	Magnesium chloride	BP	magnesium chloride hexahydrate	BP	
95409	Magnesium lactate	MAR	magnesium lactate dihydrate	BP	
54398	Magnesium phosphate	USP	magnesium phosphate pentahydrate	USPM	

ID	Ingredient name	Ref	New ingredient name	New ref	Dual labelling?
92140	Magnesium phosphate - tribasic anhydrous	MI	magnesium phosphate tribasic	MI	
68917	Magnesium sulfate	BP	magnesium sulfate heptahydrate	BP	
89305	Maldison	TGA	malathion	BP	
70177	Manganese aspartate	ICID	manganese diaspartate	ICIDM	
54416	Manganese chloride	USP	manganese chloride tetrahydrate	USPM	
68918	Manganese sulfate	BP	manganese sulfate tetrahydrate	BPM	
54455	Meglumine diatrizoate	BP	diatrizoate meglumine	USP	
54460	Meglumine iothalamate	BP	iotalamate meglumine	USANM	
54461	Meglumine iotroxate	BAN	iotroxate meglumine	USAN	
54462	Meglumine ioxaglate	BAN	ioxaglate meglumine	USAN	
72290	Meglumine pentetate	BP	pentetate meglumine	BPM	
54478	Menthyl acetate	MI	l-menthyl acetate	BPM	
54495	Mercaptopurine	BP	mercaptopurine monohydrate	BP	
81335	meta-Cresol	MI	metacresol	BP	
61429	Methyl sulfide	MI	dimethyl sulfide	MI	
54620	Methyldopa	BP	methyldopa sesquihydrate	BPM	
100645	Methyldopa anhydrous	BP	methyldopa	INN	
54707	Metoclopramide hydrochloride	BP	metoclopramide hydrochloride monohydate	BPM	
90099	Metoclopramide hydrochloride anhydrous	BP	metoclopramide hydrochloride	CAS	

ID	Ingredient name	Ref	New ingredient name	New ref	Dual labelling?
54732	Minocycline hydrochloride	BP	minocycline hydrochloride dihydrate	BP	
77552	Monosodium glutamate	USP	monosodium glutamate monohydrate	USPM	
54763	Morphine hydrochloride	BP	morphine hydrochloride trihydrate	BPM	
68482	Morphine sulfate	BP	morphine sulfate pentahydrate	BPM	
94770	Mussel - green lipped	MDF	green lipped mussel	MDF	
54798	Naloxone hydrochloride	BP	naloxone hydrochloride dihydrate	BPM	
106577	Naloxone hydrochloride anhydrous	BP	naloxone hydrochloride	BAN	
96621	Neopentyl glycol dicaprylate/dicaprate	ICID	neopentyl glycol dioctanoate/didecanoate	ICIDM	
93223	Noradrenaline	BAN	noradrenaline (norepinephrine)	BP	
54907	Noradrenaline acid tartrate	BP	noradrenaline (norepinephrine) acid tartrate monohydrate	BPM	
100593	Noradrenaline acid tartrate (Norepinephrine acid tartrate)	BP	noradrenaline (norepinephrine) acid tartrate monohydrate	BPM	
84708	Octyl triazone	ICID	ethylhexyl triazone	ICID	
54972	Oestradiol	BAN	estradiol	BP	
97672	Oestradiol hemihydrate	BAN	estradiol hemihydrate	BP	
54976	Oestradiol valerate	BAN	estradiol valerate	INN	
54977	Oestriol	BAN	estriol	BP	
54978	Oestrogens - conjugated	USP	conjugated estrogens	BP	
54979	Oestrone	BAN	estrone	INN	

ID	Ingredient name	Ref	New ingredient name	New ref	Dual labelling?
94246	Oestrone sulfate - sodium	USAN	estrone sulfate sodium	USAN	
55030	Oxethazaine	BP	oxetacaine	INN	
55037	Oxpentifylline	BP	pentoxifylline	INN	YES
57963	Paraffin - soft white	BP	white soft paraffin	BP	
73811	Paraffin - soft yellow	BP	yellow soft paraffin	BP	
92755	Pentaerythrityl tetraoctanoate	ICID	pentaerythrityl tetralaurate	ICID	
55136	Pentamidine isethionate	BP	pentamidine isetionate	BP	
55166	Pergolide mesylate	BAN	pergolide mesilate	BP	
55170	Pericyazine	BAN	periciazine	INN	
55214	Phenobarbitone	BP	phenobarbital	INN	YES
55215	Phenobarbitone sodium	BP	phenobarbital sodium	INN	YES
55234	Phentolamine mesylate	BP	phentolamine mesilate	BP	
56532	Phytic acid	MI	fytic acid	INN	
81933	Piperazine oestrone sulfate	MAR	estropipate	BP	YES
91937	Polystyrene sulfonate	USP	polystyrene sulfonate hydrogen	USPM	
91938	polystyrene sulfonate - hydrogen	USP	polystyrene sulfonate hydrogen	USPM	
55421	Potassium acid tartrate	MAR	potassium hydrogen tartrate	BP	
55434	Potassium clorazepate	BAN	dipotassium clorazepate	BP	
94109	PPG-5-laureth-5	ICID	PPG-5-lauromacrogol 250	ICIDM	

ID	Ingredient name	Ref	New ingredient name	New ref	Dual labelling?
99013	Pramipexole hydrochloride	BAN	pramipexole dihydrochloride	BPM	
106783	Pramipexole hydrochloride monohydrate	BAN	pramipexole dihydrochloride monohydrate	BP	
55500	Procaine penicillin	BP	procaine benzylpenicillin	BP	YES
55508	Prochlorperazine mesylate	BP	prochlorperazine mesilate	BP	
104581	Propylene glycol dicaprate	ICID	propylene glycol didecanoate	ICIDM	
73569	Propylene glycol dicaprylate/dicaprate	ICID	propylene glycol dioctanoate/didecanoate	ICIDM	
92183	PVP/VA Copolymer	ICID	copovidone	BP	
77612	Quinine bisulfate	BP	quinine bisulfate heptahydrate	BPM	
82015	Quinine sulfate	BP	quinine sulfate dihydrate	BPM	
102239	R,S-alpha Lipoic acid	CAS	alpha lipoic acid	USP	
68280	Retinyl acetate	BP	retinol acetate	INNM	
63235	Retinyl palmitate	BP	retinol palmitate	INNM	
55685	Rutin	MI	rutoside	INN	
55696	Salcatonin	BP	calcitonin (salmon)	INN	YES
55707	Samarium	MI	samarium (153Sm)	TGA	
96777	Saquinavir mesylate	BAN	saquinavir mesilate	BP	
55783	Sodium calciumedetate	BP	sodium calcium edetate	INN	
55785	Sodium carbonate anhydrous	BP	sodium carbonate	BPM	
90041	Sodium citrate anhydrous	BP	sodium citrate	BP	

ID	Ingredient name	Ref	New ingredient name	New ref	Dual labelling?
55801	Sodium diatrizoate	BP	sodium amidotrizoate	BP	
91696	sodium phosphate - dibasic	USP	dibasic sodium phosphate heptahydrate	USP	
90080	Sodium phosphate - dibasic anhydrous	USP	dibasic sodium phosphate	USP	
92544	sodium phosphate - monobasic	USP	monobasic sodium phosphate	USPM	
103327	Sodium phosphate - monobasic anhydrous	USP	monobasic sodium phosphate	USPM	
55889	Sodium stearyl 2-lactylate	ICID	sodium stearoyl lactylate	ICID	
69098	Sodium sulfate	BP	sodium sulfate decahydrate	BPM	
93372	Sodium sulfate anhydrous	BP	sodium sulfate	BPM	
93373	Sodium sulfite anhydrous	BP	sodium sulfite	BPM	
82070	Sodium thiosulfate	BP	sodium thiosulfate pentahydrate	BPM	
105481	Sorafenib tosylate	INN	sorafenib tosilate	USAN	
74339	TEA-lauryl sulfate	ICID	trolamine lauril sulfate	ICIDM	
56087	Testosterone enanthate	BP	testosterone enantate	BP	
100582	Tetracaine hydrochloride (Amethocaine hydrochloride)	BP	tetracaine hydrochloride	BP	YES
56101	Tetracosactrin	BP	tetracosactide	INN	YES
56115	Tetrahydrozoline hydrochloride	BAN	tetryzoline hydrochloride	BP	
102869	Thiamine phosphate acid ester chloride dihydrate	MI	monophosphothiamine dihydrate	CAS	
89496	Thiamine phosphoric acid ester chloride	MI	monophosphothiamine	INN	

ID	Ingredient name	Ref	New ingredient name	New ref	Dual labelling?
56159	Thioguanine	BP	tioguanine	INN	
56275	Triethanolamine	BP	trolamine	INN	
74920	Triethanolamine lauryl sulfate	ICID	trolamine lauril sulfate	ICIDM	
56279	Triethanolamine salicylate	ICID	trolamine salicylate	ICIDM	
56288	Trimeprazine tartrate	BP	alimemazine tartrate	BP	YES

Appendix C: List of submissions received in response to 2013 public consultation

- ACCORD Australasia (ACCORD)
- AMWAY
- Australian Self-Medication Industry Inc (ASMI)
- Baxter Healthcare Pty Ltd (Baxter)
- BioMedica Nutraceuticals (BioMedica)
- Complementary Healthcare Council of Australia (CHC)
- Consumers Health Forum Australia (CHF)
- Cosmetic Toiletry and Fragrance Association of New Zealand (CTFA)
- Generic Medicines Industry Association (GMiA)
- GlaxoSmithKline (GSK)
- Johnson & Johnson Pacific (J&J)
- Key Pharmaceuticals
- Medicines Australia
- Medicines New Zealand
- Mublasat, Omar – Pharmacist, Royal Prince Albert Hospital
- Mylan NZ
- Nestle Australia Limited (Nestle)
- New Zealand Self-Medication Industry (NZSMI)
- Novo Nordisk Pharm (Novo)
- NPS MedicineWise (NPS)
- NSW Therapeutic Advisory Group (NSW TAG)
- Pfizer Australia (Pfizer)
- The Pharmacy Guild Australia (The Guild)
- SA Health
- The Society of Hospital Pharmacists of Australia (SHPA)
- and six anonymous submissions

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Reference/Publication #