



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

International Harmonisation of Ingredient Names (IHIN)

Consultation paper

Version 1.0, May 2013

TGA Health Safety
Regulation



About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- 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), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <www.tga.gov.au>.

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Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Management and Coordination, OSE	May 2013

Contents

Introduction	6
Regulation of medicine ingredient naming in Australia	6
International standards for naming	7
The importance of harmonisation	7
Education and stakeholder engagement	8
About this consultation	9
What are the objectives of this consultation?	9
What is outside of the scope of the consultation?	9
Have your say	10
What will the TGA do with your comments?	10
Proposed changes to ingredient names	11
Summary of proposed name changes	11
Active ingredients	13
Excipients	13
Proposed implementation of Ingredient name changes	14
TGA Ingredients database	14
Implications	14
ARTG registrations and listings	14
Label requirements	15
Names proposed for dual labelling	15
Product Information (PI) and Consumer Medicine Information (CMI)	16
Implications for Consumers and healthcare professionals	16
Implications for Sponsors	17
Changes to Legislative Instruments	18
Implications	18
Proposed transitional arrangements	18
Implications	19

TGA approved terminology for medicines	20
Update to the TGA Approved terminology for medicines _____	20
Medicine ingredient names and the transition to ANZTPA	21
Implications for New Zealand in the lead up to ANZTPA _____	21
Consultation on medicine ingredient naming policy for ANZTPA ____	21
Glossary of terms	22
Appendix 1: All proposed ingredient name changes	24
Appendix 2: Prescription medicines active ingredients	45
Appendix 3: Registered over-the-counter medicines active ingredients	52
Appendix 4: Sunscreen active ingredients	56
Appendix 5: Registered complementary medicines active ingredients	57
Appendix 6: Listed medicines active ingredients	58
Appendix 7: ABNs	62
Appendix 8: Export Only medicines active ingredients	63
Appendix 9: Excipient ingredients	69
Appendix 10: Names proposed for dual labelling	82

Introduction

Regulation of medicine ingredient naming in Australia

The Therapeutic Goods Administration (TGA) is the Australian Government agency responsible for making decisions about whether to approve a therapeutic good for supply in Australia. The TGA regulates a range of therapeutic goods, including medicines, medical devices and biologicals. The focus of this consultation is medicines, specifically the names of ingredients used in the formulation of prescription medicines, over the counter medicines (including sunscreens), both registered and listed complementary medicines, and medicines for export only.

As required in the Therapeutic Goods Regulations 1990 (the Regulations), the TGA develops and maintains lists of Australian approved terminology for medicines, including approved names for ingredients used in medicines. Australian approved terminology has been developed because no single internationally agreed list or primary reference covers all substances or terms used, or likely to be used, in therapeutic goods supplied in Australia. The TGA Ingredients database contains a list of approved terminology for ingredients, and is publicly accessible via the [TGA eBS website](http://www.ebs.tga.gov.au)¹.

Use of approved terminology ensures accuracy and consistency in the information compiled in the Australian Register of Therapeutic Goods (ARTG), a comprehensive database of information about all therapeutic goods supplied in Australia or exported from Australia. The ARTG can be accessed through the [TGA eBS website](http://www.ebs.tga.gov.au). Consistency in naming helps people to retrieve information from the ARTG, helps health professionals and the public to compare similar goods, and avoids the risk of confusion between goods. Consistent naming also facilitates interoperability with other health related tools such as eHealth and the Pharmaceutical Benefits Scheme (PBS).

Approved terminology must be used:

- when sponsors submit applications for registration, listing and export of medicines, and notification of proprietary ingredients
- in records of medicine formulations included in the ARTG
- on labels for medicines
- in Product Information, Consumer Medicine Information and other product literature where use of approved terminology is required.

Australian approved names are derived from reputable international publications, such as World Health Organization lists and international pharmacopoeias. This ensures that Australian naming policy is consistent with other regulators worldwide.

For further guidance on the TGA policies and processes around naming, please see the new update to *TGA Approved Terminology for Medicines* which has been published for comment as part of this consultation.

¹ <<http://www.ebs.tga.gov.au>>



Legislative basis for naming

The Therapeutic Goods Regulations 1990 (the Regulations) provide for the use of approved names for ingredients used in medicines.

Therapeutic Goods Order No. 69—*General requirements for labels for medicines* specifies that all medicine labels are required to list the approved name of the active ingredient(s) found in the medicine.

Section 23 of the *Therapeutic Goods Act 1989* (the Act) requires applications for registration of restricted medicines (that is, prescription medicines and some over-the-counter medicines) to be accompanied by a Product Information document. The Product Information must be in a form approved under s. 7D of the Act and must contain the Australian approved name of each ingredient. The Regulations state that the Consumer Medicine Information accompanying the product must be consistent with the Product Information.

International standards for naming

International Non-proprietary Names (INNs) are maintained by the World Health Organisation and currently serve as the default global reference for medicines ingredient nomenclature. Ingredient naming policy was previously agreed by regulatory agencies from Europe, the USA and Japan in the mid 1990's. This policy is for the use of one ingredient name for a substance worldwide, rather than multiple names for single ingredients derived from numerous reference sources (e.g. pharmacopoeias) and naming conventions. The UK underwent an ingredient name harmonisation process in 2003, at which time British Approved Names (BANs) and names of ingredients in the British Pharmacopoeia (BP) were updated to reflect international naming policy. The TGA will apply the lessons learnt from this process when implementing the harmonisation of the TGA Ingredients database.

The importance of harmonisation

The TGA has routinely used INNs, where available, for new medicine ingredients in Australia since 2002. However, a list of approximately 472 ingredient names have been identified (added to the TGA Ingredient database prior to 2002,) that are not consistent with international standards. The TGA has been working on the complex and important task of bringing these medicine ingredient names into line with the INN system through the International Harmonisation of Ingredient Names (IHIN) project.

The ingredient names included in the list of ingredients proposed for harmonisation cover chemical (active and excipient) and some biological (active) ingredients used in medicines that are currently supplied in Australia or are medicines for Export Only. The IHIN project aims to update these ingredient names to reflect INN policy. This will have the benefit of:

- ensuring that only one name is used to specify an ingredient, to avoid confusion
- each name clearly and unambiguously identifying the substance being named

- ensuring consistency of ingredient names with international conventions
- ingredients being defined in such a way that a laboratory could determine if a substance that is used as an ingredient in a medicine meets the definition for that name²
- promoting international trade (interchangeable labelling)
- providing clarity to industry on TGA requirements for naming, through updated guidance documents

The harmonisation will also facilitate the regulatory practices of the TGA through convergence with international regulatory agencies and by facilitating a whole-of-government approach to naming.

Increased consistency will be beneficial to consumers and healthcare professionals as well as the pharmaceuticals industry, as certain ingredients must be specified on the labeling and Product Information or Consumer Medicine Information documentation provided with medicines.

The lists of names which TGA proposes to harmonise are provided for comment as appendices to this consultation paper:

- All proposed ingredient name changes - [Appendix 1](#)
- prescription medicine active ingredients - [Appendix 2](#)
- registered over-the-counter active ingredients - [Appendix 3](#)
- sunscreen active ingredients - [Appendix 4](#)
- registered complementary medicines active ingredients - [Appendix 5](#)
- listed medicine active ingredients - [Appendix 6](#)
- Approved Biological Names (ABNs) - [Appendix 7](#)
- medicines for export only active ingredients - [Appendix 8](#)
- excipients - [Appendix 9](#)
- names proposed for dual labelling - [Appendix 10](#)

Note that several ingredients may appear in more than one of these lists.

After this consultation, the agreed name changes will be implemented in the TGA Ingredients database. The implementation of these changes is planned to begin in 2014.

Education and stakeholder engagement

A program of engagement with consumers, healthcare professionals and industry is planned to support the harmonisation process. This is expected to begin in late 2013. This will include an educative program with the aim of familiarising consumers and healthcare professionals with the new ingredient names to minimise any potential confusion.

² This relates only to the ability to unambiguously identify the ingredient, and not to the quality of the product containing the ingredient.

About this consultation

What are the objectives of this consultation?

The proposal put forward in this consultation is to harmonise the names of some ingredients contained within medicines, not the names of the medicines themselves. The vast majority of the proposed ingredient name changes are minor, consisting of a single letter change (e.g. amoxycillin to amoxicillin; oestrogen to estrogen; cholecalciferol to colecalciferol).

The TGA recognises that the proposed changes will affect sponsors of the following products:

- prescription medicines
- over the counter medicines (including sunscreens)
- complementary medicines (both registered and listed)
- Export Only medicines

Consumers who use products that contain these ingredients, as well as healthcare professionals who prescribe and dispense them, may also be affected by the proposed changes.

Feedback received from these different stakeholder groups as part of this consultation will be used to determine an appropriate strategy to implement the changes in a way that presents the least possible inconvenience to stakeholders.

In order to do this, the TGA needs to understand the possible impacts of the harmonisation of ingredient names for consumers, healthcare professionals and sponsors. Through this consultation the TGA would like to:

- identify issues that might be faced by these different stakeholder groups as a result of the harmonisation
- use feedback received to help devise appropriate mechanisms to implement the changes
- seek feedback on an update to the document *TGA Approved terminology for medicines*

What is outside of the scope of the consultation?

The following matters are outside of the scope of the proposed harmonisation and, although the TGA may note any submissions received regarding these issues for future reference, they will not be considered as part of this consultation.

- the harmonisation of herbal ingredient names
- names of ingredients to be included in formulated medical devices
- ingredients specifically for products regulated under the biologicals framework
- the review conducted on labelling and packaging requirements
- trade names

Have your say

The TGA is seeking feedback on the proposed changes to ingredient names. Interested stakeholders are encouraged to provide a response to the general questions relating to the proposed regulatory changes. Stakeholders may respond to as many or as few of the questions as they wish and may provide additional information on issues not asked in the questions.

In addition to responses to the general questions for the proposed changes, the TGA is seeking industry specific information on the key issues of this consultation. In particular for each of the issues, industry and other interested stakeholders are invited to review and comment on the relevant recommendations. Responses should include:

- Whether or not you support the proposed changes. If you do not support a change, you may make suggestions for an alternative acceptable to you and provide rationales for the commentary.
- An assessment of how the proposed change will impact on you or your business. That is, what are the likely benefits or costs to you or your business (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.

Submissions to the general questions and industry specific information should be lodged electronically to ihin@tga.gov.au, or if hardcopy is preferred please mail your submissions to TGA International Harmonisation of Ingredient Names, PO Box 100, Woden, ACT, 2606.

The closing date for submissions is close of business **Wednesday, 10 July 2013**.

What will the TGA do with your comments?

Submissions will be acknowledged as they are received. All submissions received will be placed on the TGA website, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN-CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission coversheet.

For submissions made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA website.

In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission, you must specifically request this in the space provided on the submission coversheet.

At the close of the consultation period, the TGA will collate and analyse submissions on matters that are within the scope of this consultation. An update on the progress of the review and expected timeframes for the TGA response to the comments received will be provided on the TGA website after the close of the consultation period.

The TGA will make any refinements or amendments to the proposed options as appropriate. The outcomes of these considerations will be published on the TGA website. At this stage, the TGA will also consider appropriate transition arrangements for the medicines industry, healthcare professionals and consumers. A transitional period will be allowed for industry to comply with the changes.

Proposed changes to ingredient names

A proposed list of ingredient names was recommended for harmonisation by two groups of TGA experts. One group reviewed all Australian Approved Names (AANs) in the Ingredients database, and the other group reviewed all Australian Approved Biological Names (ABNs). If an ingredient had a specific INN, this name was recommended as the harmonised name. The experts also considered if the current approved name aligned with INN naming policies, such as how salts and other derivatives of INNs are named. New names were recommended based on this policy. The types of changes being proposed are summarised in Table 1. The experts then identified the most appropriate source to use as a specific reference for each of the names—this is consistent with current TGA naming procedures. Several errors were identified during the course of reviewing the Ingredients database, such as duplications, typographical errors and so on. The TGA is taking the opportunity to make a number of corrections to ingredient names containing errors. These corrections are also included in [Appendix 1](#).

Due to the complexity of the review of each individual ingredient name, not all names requiring harmonising may have been identified, and the TGA would appreciate being notified of any exclusions.

References used to define each name have also been checked for consistency with TGA naming policy. The TGA proposes to update only the references for several ingredients. That is, for several ingredient names that are currently consistent with INN policy, the reference will be updated, but the name itself will remain unchanged.

The review has resulted in 472 proposed ingredient name changes. Detail about what kinds of changes have been applied can be found in the following table (Table 1). A comprehensive list of all ingredient name changes is given in [Appendix 1](#). The list has been further divided for ease of identification, as per Table 2.

Summary of proposed name changes

Table 1: Summary of proposed name changes

Change type	Source of change	INN policy
If an INN reference exists for an ingredient, the name will be harmonised with the INN.	INN	ü
Derivatives of a substance – if the parent substance name is changing to an INN, the name will be harmonised with the INN.	INN	ü

Change type	Source of change	INN policy
Inclusion of hydration state, e.g. 'monohydrate'. 'Anhydrous' is the default, and does not need to be stated	<i>International Non-proprietary Names Modified</i> ³ (INNM), Section IV, Paragraph 14, page 8.	ü
Where available, changing a non-pharmacopoeial reference to a pharmacopoeial reference or INN.	international harmonisation	ü
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, · lauryl to lauril · oestrogen to estrogen · cholecalciferol to colecalciferol	<i>Guidelines on the Use of INNs for Pharmaceutical Substances</i> , Annex 2, Paragraph 7. (INNM, Section II, Paragraph 7 gives examples)	ü
Use of 'macrogol' terminology rather than 'PEG'	INNM, Section IX, Paragraph 27, page 13.	ü
The use of isolated numbers and letters should be avoided, as should hyphens (unless required for chemical structure)	<i>Guidelines on the Use of International Non-proprietary Names (INNs) for Pharmaceutical Substances</i> , Annex 2, Paragraph 6.	ü
Avoiding the use of names that are in 'common' use	<i>Guidelines on the Use of INNs for Pharmaceutical Substances</i> , Annex 2, Paragraph 1.	ü
Word order for salts and other derivatives – derivative is specified after the parent substance (e.g. etidronate disodium)	INNM	ü
Use of common name for metals rather than Latin (e.g. use of 'iron' rather than 'ferrous')	TGA naming policy – the use of common names is more readily understood by consumers.	
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 – the addition of the oxidation state is more specific	

The last two changes in table 1 referring to metallic substances are not based on INN policy. However they are not contrary to INN policy, as there is currently no specific INN guidance on how to name metallic substances, and both common and Latin names for metals appear in INNs.

³ <<http://www.who.int/medicines/services/inn/publication/en/index.html>>

Active ingredients

Several active ingredients included in the formulation of prescription medicines, over the counter medicines, complementary (both registered and listed) medicines, and export only medicines are proposed for harmonisation. Most of the active ingredients proposed for harmonisation are AANs, and six are ABNs. There are seven proposed name changes to sunscreen active ingredients ([Appendix 4](#)). Of these, one change is because the existing reference has changed the name of the substance. The other six changes result from adopting the INN for the substance, or applying INN naming conventions.

Excipients

Several excipients included in the formulation of prescription medicines, over the counter medicines, complementary (both registered and listed) medicines and export only medicines are proposed for harmonisation. [Appendix 9](#) states which excipients in the list of proposed name changes are present in each of these different regulatory categories.

The following table specifies how many name changes are proposed for which type of ingredient. The full list for each is provided in the appendix shown. Note that several ingredient names appear in more than one of these lists.

Table 2: Number of ingredients proposed for harmonisation

Type of Ingredient	Number of ingredients proposed for harmonisation	Complete list provided at:
All proposed ingredient name changes	472	Appendix 1
prescription medicine active ingredients	155	Appendix 2
registered over-the-counter active ingredients	90	Appendix 3
sunscreen active ingredients	10	Appendix 4
registered complementary medicines active ingredients	19	Appendix 5
listed medicine active ingredients	80	Appendix 6
ABNs	6	Appendix 7
export only active ingredients	118	Appendix 8
excipients	262	Appendix 9
names proposed for dual labelling	34	Appendix 10

General questions on the proposed name changes

1. Looking at all the lists of proposed ingredient name changes, do you foresee any specific concerns or benefits as a result of any of the proposed name changes?

Proposed implementation of Ingredient name changes

TGA Ingredients database

The TGA proposes to update the TGA Ingredients database in late 2013 to use the harmonised names as the approved name for the ingredients specified in the lists provided in this document. The updates to the TGA Ingredients database will involve including any previously used names as synonyms for reference and to allow the approved name to be found easily.

Implications

After the TGA Ingredients database is updated, no new products entered onto the ARTG will contain the pre-harmonised ingredient names. However, some ARTG entries for existing products will use names of active or excipient ingredients that no longer match the approved name. This means that these ARTG entries, including labelling and Product Information or Consumer Medicine Information documents, will need to be updated to reflect the harmonised ingredient names (see the following sections [ARTG registrations and listings](#) and [proposed transitional arrangements](#) for more detail).

There may be more than one name for an ingredient in the database after the harmonisation takes place. One of these duplicate ingredient names will be deactivated in the database, and no longer be available for use in new products. Only the harmonised name will then be available for use in products. For example, 'rutin' is proposed to be changed to 'rutoside'; when 'rutoside' is added at harmonisation, 'rutin' will be deactivated by the TGA, and used as a synonym for 'rutoside'. Any Ingredient names that are contained in current ARTG entries will not be deactivated until after the sponsors of the affected products have applied to the TGA to update these entries (see [Implications for sponsors](#)).

ARTG registrations and listings

The ARTG entry for a product contains information for that product, including details about the formulation, which lists the active and excipient ingredients. If an ingredient name is changed as part of the harmonisation, the formulation details for ARTG entries that contain harmonised ingredients will need to be updated to reflect the new names. This includes ARTG entries for both registered and listed products. For more detail, see the [Implications for sponsors](#).

When the ARTG entries are updated, other changes may need to be made, as described in the following sections.

Label requirements

All medicines, except medicines for Export Only, are required to comply with the [Therapeutic Goods Order No. 69—General standard for labels for medicines](#)⁴ (TGO 69). This order specifies the requirements for the labelling of medicines. The approved name of the active ingredient must be stated on the main label for all registered medicines (prescription medicines, over the counter medicines) and listed medicines (sunscreens and complementary medicines). This includes all label types i.e. main and secondary product labels, small container labels, individually wrapped goods, strip, blister and dial dispenser packs, ampoules etc.

For each label, the following may be affected when changes are made to ingredient names:

- **Active ingredients** – all labels are required to include the name of the active ingredient that is approved for inclusion in the Australian Approved Names List.
- **Excipients** – the requirement to include excipient ingredients on the label varies according to product type and the requirements of TGO 69 (e.g. lactose to lactose monohydrate).

In addition to the above, TGO 69 also has specific requirements for specific product types and dosage forms. For example, the following may be affected by the proposed harmonisation changes:

- **Preparations for ophthalmic use** (medicines to treat eye conditions) – the names of any antimicrobial preservative are required to be on the label.
- **Preparations for use on skin or mucous membranes** (such as creams or ointments to be applied to the skin) – the names of any antimicrobial preservatives are required to be on the label.
- **Biological medicines** – the names of antimicrobial preservative in the goods, the name of any adjuvants in the goods, and the name of the cell culture substrate or any residual antibiotic present are required to be on the label.
- **Injections** – the names of all excipients are required to be on the label (see TGO 69 for further detail).

The TGA is concurrently conducting a review on TGO 69 and the packaging and labelling requirements for medicines and is conscious of the impact this will have on sponsors. As a means to minimise the impact on stakeholders, the TGA is considering coordinating the implementation of ingredient name changes required as part of IHIN with changes required for the packaging and labelling review.

Names proposed for dual labelling

Thirty three substances (of 472 total changes) that are active ingredients in prescription medicines have been identified as possibly having a higher clinical risk associated with the proposed changes as the new names are significantly different to the current approved names. These may pose a greater risk to consumers if they are used incorrectly. For example, adrenaline – this ingredient is known as adrenaline in countries like Australia and the UK, but the INN for this ingredient is epinephrine. To minimise the risk of the wrong medicine being used in such cases, the TGA proposes that dual labelling is used for these 34 high risk substances. That is, both the currently approved name and the proposed new name will be

⁴<<http://www.tga.gov.au/industry/legislation-tgo.htm>>

required to be on the label. For example, dual labelling for adrenaline could look like 'adrenaline (epinephrine)'.

The TGA proposes that dual labelling be used for these 34 ingredients for a period of 5 years following the implementation of the changes to ingredient names in the TGA Ingredients database. During this period the Australian approved name for these ingredients will be the dual name required to be on the label, e.g. adrenaline (epinephrine).

The proposed dual labelling is considered an important part of the transition to the new name, to help minimise any potential risk and confusion associated with the ingredient name changes. [Appendix 10](#) contains the complete list of ingredients proposed for dual labelling.

General questions on the proposal for dual labelling

2. What do you think about the proposal to include both the current approved name and the proposed new name (dual labelling) for substances of high clinical significance?
3. Is the proposed time period for using dual labelling appropriate?

Product Information (PI) and Consumer Medicine Information (CMI)

As for labelling, if the Product Information or Consumer Medicine Information specifies an ingredient name that has been harmonised, this documentation will need to be updated to reflect the new name, i.e. the Australian approved name for that ingredient.

Implications for Consumers and healthcare professionals

When the harmonisation takes place, the names for ingredients contained in medicines (not the names of the medicine products themselves) on product labels, PIs, CMIs and other documentation will gradually change over time, as each ARTG entry is updated. Healthcare professionals and consumers need to be aware of these changes, so that the correct medicine is prescribed and taken.

Harmonising medicine ingredient names with international practice is expected to benefit healthcare professionals, for example, those who have trained overseas will be more likely to be familiar with the new terminology being introduced in Australia. The TGA wants to ensure that healthcare professionals are aware of the changes to the affected ingredient names to allow them to provide accurate advice to consumers and support the transition to the new names (see [Education and stakeholder engagement](#)).

General questions on the potential impact of the proposed name changes

4. Do you agree that harmonising the names of ingredients with international practice will be beneficial?
5. Will having international naming consistency assist in clinical practice?

Implications for Sponsors

The TGA wants to ensure that the changes are implemented with minimal financial and logistical impact on sponsors, so we are encouraging sponsors to provide feedback on the proposals in this document. Comment is being sought both in terms of the suggested approach for implementation, and on the specific proposed name changes (provided in the appendices). Feedback received during this consultation period will guide the TGA in how it carries out the harmonisation, which will be communicated in more detail to sponsors throughout 2013.

The ARTG entries for products that contain harmonised ingredients will need to be updated to reflect the new name. The ARTG entries will be updated using existing regulatory mechanisms depending on the nature of the changes required. For example:

- if only the ARTG entry requires updating, the variation to the ARTG may be instigated by the initiative of TGA, and the sponsor of the product will be notified of the details of the change
- in cases where the ARTG entry, as well as labelling and PI information require updating, an application to vary the ARTG entry and all other requisite documentation will need to be lodged by the sponsor of the affected products. The TGA would encourage such applications to be lodged in conjunction with other required applications to vary ARTG entries to minimise the cost to sponsors

The TGA proposes to implement a transition period (see [Proposed transitional arrangements](#)) to allow for these changes to be made.

Sponsors are asked to check the list of ingredient names proposed for harmonisation to determine if any of their products are affected. The list has been subdivided into different regulatory areas, as well as by active or excipient ingredients, to assist with this. The TGA is able to monitor affected ARTG entries that may require updating, and if necessary, can advise sponsors of the need to update their ARTG entries.

Some medicines have the active ingredient name as part of the trade name (also known as product name or proprietary name) for the product. The objective of IHIN is to harmonise the names ingredients contained within medicines, not the names of the medicines themselves. However 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 not be required by the TGA as part of the harmonisation, and would be considered to reflect a voluntary commercial decision by the sponsor of the product.

General questions on the potential impact of the proposed name changes

6. Do you agree that harmonising the names of ingredients with international practice will be beneficial?
7. Specifically, will the name changes make preparing labels and other documents for the Australian market easier, in terms of international consistency?

Changes to Legislative Instruments

TGO 69 and several other legislative instruments and standards refer to specific ingredients by name. Some of these names are proposed to be harmonised. For example,

- TGO 69 refers specifically to several substances that are proposed for harmonisation changes e.g.
 - The first schedule of TGO 69 – Excipients required to be declared on the label of medicines, (e.g. lactose to lactose monohydrate).
- Therapeutic Goods Order No. 80— Child-Resistant Packaging Requirements for Medicines (TGO 80) (e.g. frusemide changing to furosemide)
- Therapeutic Goods Regulations 1990, Schedule 2
- Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)

Implications

These documents will be updated by the TGA in time to reflect the new names. Previously used names of some ingredients, may be referenced until such a time that these are updated. Any previously used names will be included in the ingredients database as synonyms so that the approved name can be found easily. Note that the same regulatory requirements will continue to apply for the relevant ingredients, regardless of which name is used in the legislative instrument.

Proposed transitional arrangements

Changes cannot be made to affected ARTG entries until after the TGA updates the ingredient names in the TGA Ingredients database, when the harmonised names become the new Australian Approved Names. Once the ingredient database is updated to reflect the harmonised names, it will take time to then update all ARTG entries for affected products (see [ARTG registrations and listings](#), [Implications for sponsors](#)).

The TGA proposes introducing a transitional period to allow for the ARTG to be updated, including for product label changes and changes to Product Information and Consumer Medicine Information documents. The transition period is proposed as a means to reduce the impact of harmonising ingredient names on sponsors. The timing of the transition arrangements is likely to be aligned with the implementation of other TGA reforms, with the following transitional periods proposed (see Figure 1 also):

- **Updates to Labelling:** sponsors update their product labels within two years of the ingredient database updates or at the next print run or packaging artwork amendment, whichever is sooner.
- **Updates to PI and CMI documents:** sponsors request an update to the PI document within two years of the TGA ingredient database updates or as part of the next submission to the TGA, whichever is sooner. The CMI should also be updated accordingly within this time.

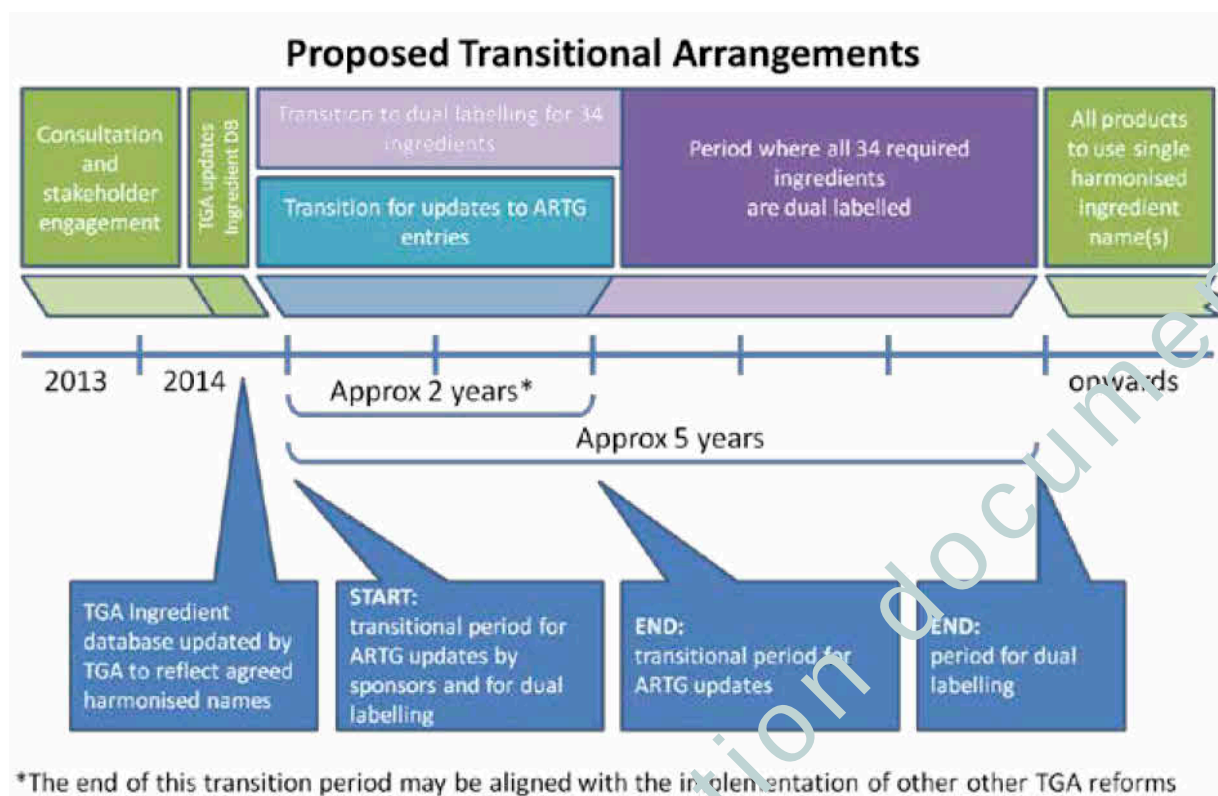


Figure 1 proposed transitional arrangements.

Implications

Sponsors for all products affected will need to have applied to the TGA to make the required changes to ARTG entries and requisite documentation by the end of the transition period (see Figure 1). At this stage the transition period is proposed to be for 2 years, but the end of this transition may be aligned with the implementation of other TGA reforms, such as the review of packaging and labelling.

If a sponsor has lodged an application to make such a change before the end of the transition period but a decision has not yet been made by the TGA, the sponsor can continue to use the old ingredient name until such a time that a decision is made.

The TGA proposes that the 5 year period for dual labelling begins concurrently with the transition period for ARTG updates. This means that the first 2 years of the proposed period for dual labelling will be transitional, to allow for the label changes to be applied (see figure 1). For the final 3 years, all affected products will be required to use dual labelling.

General question on proposed transitional period:

8. Do you agree that the proposed transitional period is sufficient to ensure associated costs, such as printing new labels, could be met through business-as-usual activities?

TGA approved terminology for medicines

TGA Approved Terminology for Medicines provides guidance on TGA policies relating to how approved names for new medicine ingredients are determined, and describes the TGA process for entering new approved names onto the TGA Ingredient database. This document, which was last updated in 2001, has been reviewed as part of the IHIN project.

Update to the TGA Approved terminology for medicines

The TGA has considered feedback from industry and other stakeholders that was received during a previous consultation exercise in preparing the update to *TGA Approved Terminology for Medicines*. This consultation was conducted in 2006 on a draft document titled 'Draft Guidelines and Policies on Australian New Zealand Therapeutic Products Authority (ANZTPA) Determination of Ingredient Names for Medicines'. Information from this draft document about current TGA naming policy has been incorporated into *TGA Approved Terminology for Medicines*, so that sponsors will have access to a single document describing TGA naming policy and procedures in detail.

Although the scope of *TGA Approved Terminology for Medicines* has not changed, the update includes significant enhancements to previous versions including:

- increased guidance about TGA naming policy and related business processes
- improved usability through a simplified layout and use of practical examples
- the removal of the 'printed' ingredients list – the current ingredients list is published on the TGA eBS website. Providing the list electronically has several advantages over a published printed version, as the database is easier to search and is regularly updated when new ingredients are added. This in turn makes *TGA Approved Terminology for Medicines* more accessible

The TGA is seeking comment on the updated guidance as part of this consultation.

General Questions on the update to TGA Approved terminology for medicines

9. Do you believe anything is missing from this document? If so, please specify.
10. Do you agree that the updated document is more user-friendly?
11. Will this update to the guidance assist you in proposing new ingredient names?
12. Are there any general concerns with the updates to the structure of *TGA Approved terminology for medicines*?

Medicine ingredient names and the transition to ANZTPA

The Australia New Zealand Therapeutic Product Agency (ANZTPA) is a joint project of the Therapeutic Goods Agency in Australia and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe). The ingredient naming policy for prescription and over-the-counter medicines outlined in *TGA Approved Terminology for Medicines* is likely to be adopted in a similar form for the purposes of the joint agency.

Implications for New Zealand in the lead up to ANZTPA

Currently New Zealand legislation requires medicine labels to include certain information, including specifying the active ingredients, but the medicines legislation does not specify which nomenclature system is to be used to identify the active ingredients.

NZ is a small market and due to economies of scale, the medicines supplied in New Zealand are often batches of product manufactured or packaged for a larger or international market. If that other market is in a country that requires medicines to be labelled as INNs, then NZ is likely to receive INN-labelled medicines. As other countries with large markets have largely adopted INN naming policies for medicines ingredients, New Zealand is receiving an increasing number of medicines labelled with INNs. Bringing the Australian market completely in line with INN policy, as outlined in this paper, should simplify things for the New Zealand market.

Consultation on medicine ingredient naming policy for ANZTPA

As previously mentioned, a [previous consultation exercise](#) was conducted in 2006 on a draft document entitled 'Draft Guidelines and Policies on Australian New Zealand Therapeutic Products Authority (ANZTPA) Determination of Ingredient Names for Medicines'. This was a joint Australia/New Zealand consultation and the policies put forward were agreed upon by both countries. It should be noted however that even though the draft guidance *TGA Approved Terminology for Medicines* also captures complementary medicines, at this stage these only apply to Australian stakeholders. The issue of the regulation of complementary medicines under the joint agency will be further discussed as the implementation for ANZTPA continues to gain momentum.

The TGA encourages stakeholders in New Zealand to provide comment on the changes proposed in this consultation paper and on the updated guidance as part of this consultation. Further information for New Zealand stakeholders can be found on the [Medsafe website](#)⁵.

⁵ <<http://www.medsafe.govt.nz>>

Glossary of terms

Definitions of key terms used in this consultation paper are provided in this section to facilitate a common understanding of the key issues and proposed regulatory options.

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

Australian Approved Name (AAN): ingredients in medicines that are chemical substances. These substances are given Australian Approved Names (chemical) (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 the 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, depending on the class of therapeutic good. If a therapeutic good is not entered on the ARTG, it cannot be supplied in Australia unless access has been granted under the special access scheme.

The ARTG is available online for anyone to view and includes the following information:

- Product name and ingredients
- Sponsor and manufacturer details
- If a medicine is registered or listed

More information on searching the ARTG can be found at: Searching the Australian Register of Therapeutic Goods (ARTG).

Complementary medicines: also known as 'traditional' or 'alternative' medicines, 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 medicine.

Excipient: An inert or inactive substance added as an ingredient to medicines.

INN (International Non-proprietary Name): A list maintained by the World Health Organization that identifies pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized 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 that are evaluated and approved for marketing in Australia based on assessment of safety and manufacturing quality. 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 are not permitted to include substances that are scheduled in the Poisons Standard and can be identified by the presence of an 'AUST L' number on the medicine label.

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

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

Non-proprietary name: the name used to describe the goods (particularly medicines) in a specific standard, including the name of the dosage form (if no standard exists, a name may comprise the AAN of the active ingredient and the name of the dosage form)

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 health care 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. Products containing substances scheduled in the Poisons Standard are evaluated as registered medicines. Registered medicines can be identified by the presence of an 'AUST R' number on the medicine label.

Stakeholder: a person, group or organisation who affects, or can be affected by, an organisation's actions.

Trade name/ Brand name: means the commercial name: (a) given to goods by the manufacturer and (b) under which the goods are supplied.

Appendix 1: All proposed ingredient name changes

Table 3: All proposed ingredient name changes

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meet INN Policy?
1	53999	2-hydroxymethylfuran	MI	furfuryl alcohol		ü
2	81918	3-phenyl propyl alcohol	PFC	phenylpropanol	USAN	ü
3	90839	4-Methylbenzylidene camphor	ICID	enzacamene	INN	ü
4	51951	6-acetyl-1,1,3,4,4,6-hexamethyl tetrahydronaphthalene	PFC	7-acetyl-1,1,3,4,4,6-hexamethyl tetrahydronaphthalene		
5	54012	8-hydroxyquinoline	MI	oxyquinoline	USAN	ü
6	51965	Acriflavine	MAR	acriflavium chloride	INN	ü
7	103505	Acrylates/steareth-20 methacrylate copolymer	ICID	acrylates/stearomacrogol 1000 methacrylate copolymer	ICID*	ü
8	58903	Actinomycin D	USAN	dactinomycin		ü
9	51982	Adrenaline	BP	epinephrine	INN	ü
10	51983	Adrenaline acid tartrate	BP	epinephrine acid tartrate	BP*	ü
11	51985	Adrenaline hydrochloride	BP	epinephrine hydrochloride	BP*	ü
12	93569	Alizarin, cyanine green F	MI	acid green 25	CI	
13	52016	Allylamyl glycollate	CAS	allyl amyl glycolate	TGA	ü
14	96.13	Alpha tocopherol	BP	dl-alpha-tocopherol	USP*	
15	96314	Alpha tocopherol acetate	BP	dl-alpha-tocopheryl acetate	USP*	
16	80265	alpha-iso-Methyl ionone	PFC	alfa-iso-methyl ionone	PFC*	ü
17	52047	Alum	BP	alum dodecahydrate	BP*	ü
18	52059	Aluminium hydroxide	MI	hydrated aluminium hydroxide	BP*	ü
19	57910	Aluminium hydroxide - dried	BP	aluminium hydroxide		ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
20	52063	Aluminium nitrate	MI	aluminium nitrate nonahydrate	BPAP*	ü
21	88051	Aluminium oxide anhydrous	MI	aluminium oxide		
22	71128	Aluminium sulfate	BP	aluminium sulfate hydrated		
23	52086	Amethocaine hydrochloride	BP	tetracaine hydrochloride		ü
24	52090	Amiloride hydrochloride	BP	amiloride hydrochloride dihydrate	RP*	ü
25	52091	Aminacrine hydrochloride	BAN	aminoacridine hydrochloride		ü
26	56667	Amlodipine besylate	BAN	amlodipine besilate		ü
27	106994	Ammonium acryloyldimethyltaurate/stearate-8 methacrylate copolymer	ICID	ammonium acryloyldimethyltaurate/stearomacrogol 400 methacrylate copolymer	ICID*	ü
28	52122	Ammonium hydroxide	MAR	strong ammonia solution/dilute ammonia solution	BP	ü
29	89500	Ammonium laurate sulfate	ICID	ammonium lauromacrogol sulfate	ICID*	ü
30	81128	Ammonium lauryl sulfate	ICID	ammonium lauril sulfate		ü
31	56480	Amoxicillin	BP	amoxicillin		ü
32	60720	Amoxicillin sodium	BP	amoxicillin sodium		ü
33	52133	Amoxicillin trihydrate	BP	amoxicillin trihydrate		ü
34	52137	Amphotericin	BP	amphotericin B	INN	ü
35	52166	Amobarbitone sodium	BP	amobarbital sodium		ü
36	52206	Antimony potassium tartrate	USP	antimony potassium tartrate trihydrate	USP*	ü
37	55337	Apomorphine hydrochloride	BP	apomorphine hydrochloride hemihydrate	BP*	ü
38	90093	Apricot kernel oil PEG-6 esters	ICID	apricot kernel oil macrogol 300 esters	ICID*	ü
39	52235	Atracurium besylate	BAN	atracurium besilate		ü
40	70757	Atropine sulfate	BP	atropine sulfate monohydrate	BP*	ü
41	96610	Bacillus Calmette and Guérin	BP	mycobacterium bovis (BCG strain)		

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
42	52278	Beclomethasone Dipropionate	BP	beclometasone dipropionate		ü
43	94769	Bee	AIN	honey bee	HPUS	
44	103481	Bee venom	HPUS	honey bee venom	AIN	
45	106112	Behenoyl polyoxyglycerides	TGA	behenoyl macrogolglycerides	USP*	ü
46	52304	Benzhexol hydrochloride	BP	trihexyphenidyl hydrochloride		ü
47	52309	Benzodihydropyrone	FCC	dihydrocoumarin		ü
48	52320	Benztropine mesylate	BP	benzatropine mesilate		ü
49	52350	Berberine hydrochloride	MAR	berberine chloride	BPAP	ü
50	103937	Bis-peg-12 dimethicone beeswax	ICID	bismacrogol 600 dimethicone beeswax	ICID*	ü
51	52414	Bretylium tosylate	BAN	bretylium tosylate	BP	ü
52	52427	Bromocriptine mesylate	BP	bromocriptine mesilate		ü
53	52448	Bupivacaine hydrochloride	BP	bupivacaine hydrochloride monohydrate	BP*	ü
54	101754	Bupivacaine hydrochloride anhydrous	BP	bupivacaine hydrochloride		ü
55	52467	Butoxyethyl nicotinate	MAR	nicoboxil	INN	ü
56	52473	Butyl aminobenzoate	USAN	butamben	USP	ü
57	95463	Butyl methoxybenzoylmethane	ICID	avobenzene	INN	ü
58	93473	C12-15 alkyl benzoate	ICID	alkyl (C12-15) benzoate	USP	ü
59	52523	Calcium chloride	BP	Calcium chloride dihydrate		ü
60	52719	Calcium citrate hydrate	MI	calcium citrate tetrahydrate	USAN*	ü
61	52538	Calcium gluconate	BP	calcium gluconate monohydrate	BP*	ü
62	52543	Calcium hydrogen phosphate	BP	calcium hydrogen phosphate dihydrate	BP*	ü
63	95202	Calcium hydrogen phosphate anhydrous	BP	calcium hydrogen phosphate	BP*	ü
64	100565	Calcium lactate anhydrous	BP	calcium lactate	BP*	ü
65	63405	Calcium sulfate	BPAP	calcium sulfate hemihydrate	BPAP*	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
66	92089	Calcium sulfate anhydrous	USP	calcium sulfate		ü
67	91543	Caldiamide sodium	BAN	caldiamide sodium hydrate	BAN*	ü
68	60531	Caprylic/capric triglyceride	ICID	medium chain triglycerides	BP	
69	52614	Carbidopa	BP	carbidopa monohydrate	BP*	ü
70	87613	Carbidopa anhydrous	BP	carbidopa	INN	ü
71	52685	Cellacephate	BP	cellacefate		ü
72	52689	Cephalexin	BP	cefalexin monohydrate		ü
73	100859	Cephalexin anhydrous	BP	cefalexin		ü
74	52691	Cephalothin sodium	BP	cefalotin sodium		ü
75	81269	Cephmandole	BAN	cefamandole	INN	ü
76	71817	Cephazolin	BAN	cefazolin		ü
77	52695	Cephazolin sodium	BAN	cefazolin sodium		ü
78	89270	Cetareth-12	ICID	cetearomacrogol 600	ICID*	ü
79	90085	Cetareth-17	ICID	cetearomacrogol 850	ICID*	ü
80	73387	Cetareth-20	ICID	cetearomacrogol 1000	ICID*	ü
81	90079	Cetareth-25	ICID	cetearomacrogol 1250	ICID*	ü
82	85415	Cetareth-30	ICID	cetearomacrogol 1500	ICID*	ü
83	81271	Cetareth-6	ICID	cetearomacrogol 300	ICID*	ü
84	94232	Ceteth-2	ICID	cetomacrogol 100	INN*	ü
85	94236	Ceteth-24	ICID	cetomacrogol 1200	INN*	ü
86	89428	Cetyl dimethicone	ICID	cetyl dimeticone	ICID*	ü
87	92177	Cetyl dimethicone copolyol	ICID	cetyl macrogol/PPG-500/1 dimeticone	ICID*	ü
88	99554	Chitosan	ICID	poliglusam	INN	ü
89	52739	Chlorbutol	BP	chlorobutanol hemihydrate	BP*	ü
90	52779	Chlorpheniramine maleate	BP	chlorphenamine maleate		ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
91	52793	Chlorthalidone	BP	chlorthalidone		ü
92	52796	Cholecalciferol	BP	colecalfiferol		ü
93	52798	Cholestyramine	BAN	colestyramine	INN	ü
94	73378	Choleth-24	ICID	cholomacrogol 1200	ICID*	ü
95	94798	Chromic chloride	USP	chromium (III) chloride hexahydrate	USP*	
96	95567	cis-3-Hexenyl caproate	PFC	cis-3-hexenyl hexanoate	PFC*	ü
97	96377	Cisatracurium besylate	BAN	cisatracurium besilate		ü
98	97439	Citric acid - anhydrous	BP	citric acid	BP*	ü
99	52917	Clomiphene citrate	BP	clomifene citrate		ü
100	73497	Coco-caprylate/caprate	ICID	coco-octanoate/docanoate	ICID*	ü
101	52959	Codeine phosphate	BP	codeine phosphate hemihydrate		ü
102	52966	Colaspase	BAN	anaparaginase	USAN	ü
103	93010	Co-methylcobalamin	MI	mecobalamin	INN	ü
104	91242	Corn oil PEG-6 esters	ICID	corn oil macrogol 300 esters	ICID*	ü
105	94811	Crystal violet CI42555	MAR	methylrosanilinium chloride	INN	ü
106	94938	Cupric acetate monohydrate	MI	copper (II) acetate monohydrate	MI*	
107	58571	Cupric chloride dihydrate	MI	copper (II) chloride dihydrate	USP*	
108	100063	Cupric citrate	MI	copper (II) citrate	MI*	
109	104902	Cupric citrate hemipentahydrate	MI	copper (II) citrate hemipentahydrate	MI*	
110	94803	Cupric oxide	MI	copper (II) oxide	MI*	
111	94806	Cupric sulfate anhydrous	MI	copper (II) sulfate	MI*	
112	94807	Cupric sulfate monohydrate	MI	copper (II) sulfate monohydrate	MI*	
113	94810	Cupric sulfate pentahydrate	MI	copper (II) sulfate pentahydrate	USP*	
114	94518	Cyanocobalamin(57Co)	BP	cyanocobalamin (57Co)	INN	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
115	53048	Cyclomethicone	USP	cyclomethicone	USP*	ü
116	53054	Cyclophosphamide	BP	cyclophosphamide monohydrate	INN*	ü
117	53057	Cyclosporin	BAN	ciclosporin		ü
118	53063	Cyproheptadine hydrochloride	BP	cyproheptadine hydrochloride sesquihydrate	BP*	ü
119	97278	Cysteamine bitartrate	BAN	mercaptamine bitartrate		ü
120	53073	Dantrolene sodium	BAN	dantrolene sodium hemiheptahydrate	INN*	ü
121	105603	DEA-C8-18 perfluoroalkylethyl phosphate	ICID	diolamine C8-18 perfluoroalkylethyl phosphate	ICID*	ü
122	70697	DEA-cetyl phosphate	ICID	diolamine cetyl phosphate	ICID*	ü
123	100780	DEA-Oleth-3 phosphate	ICID	diolamine Olomacrogol 150 phosphate	ICID*	ü
124	63559	Decan-1-ol	BPAP	decyl alcohol		ü
125	97447	Delavirdine mesylate	USAN	delavirdine mesilate		ü
126	53110	Desferrioxamine mesylate	BP	desferrioxamine mesilate		ü
127	81377	Dexamphetamine sulfate	BP	dexamfetamine sulfate	BP*	ü
128	53142	Dextromethorphan hydrobromide	BP	dextromethorphan hydrobromide monohydrate	BP*	ü
129	53146	Dextropropoxyphene napsylate	BP	dextropropoxyphene napsilate monohydrate		ü
130	68290	Diazolidinylurea	ICID	diazolidinyl urea		ü
131	91312	Diclofenac diethylammonium	BAN	diclofenac diethylamine	BP	ü
132	96353	Diethyl toluamide	ICID	diethyltoluamide	INN	ü
133	53233	Dihydroergotamine mesylate	BP	dihydroergotamine mesilate		ü
134	53248	Di-iodohydroxyquinoline	BAN	diiodohydroxyquinoline	INN	ü
135	53250	Di-isopropanolamine	USP	diisopropanolamine		ü
136	104168	Dimeglumine gadobenate	BP	gadobenate dimeglumine	BP*	ü
137	72289	Dimeglumine gadopentetate	USAN	gadopentetate dimeglumine	USP*	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
138	85525	Dimethicone 10	BP	dimeticone 10	BP*	ü
139	91502	Dimethicone 100	BP	dimeticone 100	BP*	ü
140	58347	Dimethicone 1000	BP	dimeticone 1000	BP*	ü
141	96967	Dimethicone 1510	BP	dimeticone 1510	BP*	ü
142	96336	Dimethicone 20	BP	dimeticone 20	BP*	ü
143	73472	Dimethicone 200	BP	dimeticone 200	BP*	ü
144	104415	Dimethicone 30	BP	dimeticone 30	BP*	ü
145	64435	Dimethicone 350	BP	dimeticone 350	BP*	ü
146	84714	Dimethicone 450	BP	dimeticone 450	BP*	ü
147	98939	Dimethicone 5	BP	dimeticone 5	BP*	ü
148	80998	Dimethicone 50	BP	dimeticone 50	BP*	ü
149	66689	Dimethicone copolyol	ICID	dimeticone copolyol	ICID*	ü
150	94065	Dimethicone copolyol phosphate	ICID	dimeticone copolyol phosphate	ICID*	ü
151	66554	Dimethiconol	ICID	dimeticonol	ICID*	ü
152	101709	Dimethiconol stearate	ICID	dimeticonol stearate	ICID*	ü
153	95372	Di-N propyl isocinchomerate	CAS	di-n-propyl isocinchomerate		ü
154	81428	Diphenyl methylsulfate	BAN	diphenyl methylsulfate	INN	ü
155	53315	Diphenyl ether	MI	diphenyl oxide		ü
156	102486	Disodium dimethicone copolyol sulfosuccinate	ICID	disodium dimeticone copolyol sulfosuccinate	ICID*	ü
157	53329	Disodium etidronate	BAN	etidronate disodium	BP	ü
158	74330	Disodium laurethsulfosuccinate	ICID	disodium lauromacrogolsulfosuccinate	ICID*	ü
159	103021	Disodium oleamido PEG-2 sulfosuccinate	ICID	disodium oleamido macrogol 100 sulfosuccinate	ICID*	ü
160	68222	Disodium pamidronate	BAN	pamidronate disodium	BP*	ü
161	91701	Disteareth-6 dimonium chloride	ICID	distearamacrogol 300 dimonium chloride	ICID*	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
162	102195	dl-alpha tocopherol phosphate disodium	CAS	dl-alpha-tocopheryl phosphate disodium		
163	93271	dl-alpha tocopheryl acetate	BP	dl-alpha-tocopheryl acetate	USP*	
164	59836	DMDM Hydantoin	ICID	dimethylol dimethyl hydantoin	ICID*	ü
165	60075	Docosahexaenoic acid	MAR	doconexent	INN	ü
166	97007	Dolasetron mesylate	BAN	dolasetron mesilate monohydrate	BAN*	ü
167	53367	Dothiepin hydrochloride	BP	dosulepin hydrochloride		ü
168	56553	Doxazosin mesylate	BAN	doxazosin mesilate	BP	ü
169	53373	Doxycycline hydrochloride	BP	doxycycline hyclate		ü
170	87433	Edetate dipotassium	MI	edetate dipotassium dihydrate	USAN*	ü
171	96966	Eformoterol	BAN	formoterol		ü
172	97220	Eformoterol fumarate	BAN	formoterol fumarate	BP*	ü
173	97221	Eformoterol fumarate dihydrate	BAN	formoterol fumarate dihydrate	BP	ü
174	53393	Eicosapentaenoic acid	MI	icosapent	INN	ü
175	91756	Eosine	MAR	acid red 87		
176	97830	Eprosartan mesylate	BAN	eprosartan mesilate		ü
177	53458	Ethacrynic acid	BP	etacrynic acid		ü
178	53463	Ethanolamine	BP	monoethanolamine	INN	ü
179	81464	Ether - solvent	BP	ether		ü
180	53471	Ethinylestradiol	BP	ethinylestradiol		ü
181	100719	Ethyl oenanthate	MI	ethyl enantate	INN*	ü
182	53547	Ethyl oenanthate	MI	ethyl enantate	INN*	ü
183	53515	Ethylene glycol monostearate	MAR	ethylene glycol monopalmitostearate	BP	ü
184	93304	Ethylene/VA copolymer	ICID	ethylene/vinyl acetate copolymer	ICID*	ü
185	53539	Ethylmorphine hydrochloride	BP	ethylmorphine hydrochloride dihydrate	BP*	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
186	53565	Ethinodiol diacetate	BP	etynodiol diacetate		ü
187	94793	Ferric ammonium citrate	MAR	iron (III) ammonium citrate	USP*	
188	107254	Ferric carboxymaltose	INN	iron(III) carboxymaltose	INN*	
189	94818	Ferric chloride anhydrous	MAR	iron(III) chloride	MI*	
190	94819	Ferric chloride hexahydrate	MAR	iron(III) chloride hexahydrate	BP	
191	53619	Ferric glycerophosphate	USAN	iron (III) glycerophosphate	USAN*	
192	58044	Ferric manganese peptonate	TGA	iron (III) manganese (II) peptonate		
193	92469	Ferric nitrate	BPAP	iron (III) nitrate nonahydrate	BPAP*	
194	53622	Ferric oxide	MI	iron (III) oxide	USP*	
195	53623	Ferric phosphate	MI	iron (III) phosphate	MI*	
196	53624	Ferric pyrophosphate	MI	iron (III) pyrophosphate	MI*	
197	53627	Ferrosoferric oxide	MI	iron oxide	MI*	
198	93577	Ferrosoferric phosphate	HPUS	iron phosphate		
199	53631	Ferrous fumarate	BP	iron (II) fumarate	BP*	
200	53632	Ferrous gluconate	BP	iron (II) gluconate	BP*	
201	98671	Ferrous gluconate dihydrate	BP	iron (II) gluconate dihydrate	BP*	
202	93576	Ferrous iodide	MI	iron (II) iodide	MI*	
203	53633	Ferrous lactate	MAR	iron (II) lactate trihydrate	MAR*	
204	53635	Ferrous phosphate	MAR	iron (II) phosphate octahydrate	MI*	
205	69280	Ferrous sulfate	BP	iron (II) sulfate heptahydrate	BP*	
206	68856	Ferrous sulfate - dried	BP	iron (II) sulfate	BP*	
207	59987	Flucloxacillin magnesium	BP	flucloxacillin magnesium octahydrate		ü
208	53651	Flucloxacillin sodium	BP	flucloxacillin sodium monohydrate	BP*	ü
209	53662	Flumethasone pivalate	BAN	flumetasone pivalate	BP	ü
210	81511	Flupenthixol decanoate	BAN	flupentixol decanoate	BP	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
211	90838	Flurbiprofen sodium	USP	flurbiprofen sodium dihydrate	USP*	ü
212	53730	Frusemide	BP	furosemide		ü
213	102321	Frusemide sodium	BP	furosemide sodium		ü
214	100588	Furosemide (Frusemide)	BP	furosemide		ü
215	53743	Fusidic acid	BP	fusidic acid hemihydrate	BP*	ü
216	94521	Gallium(67Ga) citrate	BP	gallium (67Ga) citrate	INN	ü
217	101812	Glucosamine sulfate-potassium chloride complex	TGA	glucosamine sulfate potassium chloride	USP	ü
218	101813	Glucosamine sulfate-sodium chloride complex	TGA	glucosamine sulfate sodium chloride	USP	ü
219	53790	Glucose	BP	glucose monohydrate	BP*	ü
220	58055	Glucose - anhydrous	BP	glucose	BP*	ü
221	53795	Glutaraldehyde	BP	glutaral	INN	ü
222	94891	Glycerol triacetate	BPA?	triacetin		ü
223	53805	Glyceryl mono-oleate	MAR	glyceryl monooleate	USP	ü
224	53813	Glycol salicylate	MAR	hydroxyethyl salicylate	BP	ü
225	61974	Glycol stearate	ICID	ethylene glycol monopalmitostearate		ü
226	73454	Glycolic acid	MI	glycolic acid		ü
227	53814	Glycopyrrolate	USP	glycopyrronium bromide	INN	ü
228	85484	Glycyrrhetic acid	ICID	enoxolone	BP	ü
229	53839	Guaiphenesin	BP	guaifenesin	INN	ü
230	93306	Haematoporphyrin	MAR	hematoporphyrin	MI	ü
231	95160	Haematoporphyrin dihydrochloride	MAR	hematoporphyrin dihydrochloride	MI*	ü
232	53856	Halethazole	BAN	haletazole	INN	ü
233	93288	Heparinoid	MAR	heparinoids		ü
234	72588	Hercolyn	PFC	methyl hydrogenated rosinat		ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
235	53892	Hexachlorophane	BP	hexachlorophene		ü
236	53899	Hexamidine isethionate	MAR	hexamidine isoetionate		ü
237	53903	Hexamine hippurate	BAN	methenamine hippurate		ü
238	53994	Hydroxyethylcellulose	BP	hyetellose	INN	ü
239	53995	Hydroxyethylmethylcellulose	BP	hymetellose	INN	ü
240	81585	Hydroxyethylrutosides	MAR	oxerutins	BAN	ü
241	98418	Hydroxypropyl beta cyclodextrin	USP	hydroxypropylbetadex	BP	ü
242	67610	Hydroxypropylcellulose	BP	hyprolose	INN	ü
243	81590	Hydroxyquinoline sulfate	MAR	oxyquinoline sulfate	USP	ü
244	54017	Hydroxyurea	BP	hydroxy carbamide		ü
245	75213	Hyoscyamine sulfate	BP	hyoscyamine sulfate dihydrate	BP*	ü
246	102968	Imatinib mesylate	INN	imatinib mesilate	INN*	ü
247	93243	Indium(111In) chloride	USAN	indium (111In) chloride	USP*	ü
248	94522	Indium(111In) hydroxyquinoline	BP	indium (111In) hydroxyquinoline	USP*	ü
249	94523	Indium(111In) pentetate	BP	indium (111In) pentetate	BP*	ü
250	54059	Indomethacin	BP	indometacin		ü
251	56468	Indomethacin sodium	USP	indometacin sodium trihydrate	INN*	ü
252	54037	Insulin - human	BP	insulin		ü
253	104.69	Iobenguane(123I) sulfate	USAN	iobenguane (123I) sulfate	USAN*	ü
254	94069	Iodobenzylguanidine(131I) sulfate	USAN	iobenguane (131I) sulfate		ü
255	96978	Ipratropium bromide	BP	ipratropium bromide monohydrate	INN*	ü
256	98828	Ipratropium bromide anhydrous	BP	ipratropium bromide	INN	ü
257	97484	Irinotecan hydrochloride	USAN	irinotecan hydrochloride trihydrate	USP	ü
258	69531	Iron polymaltose	MAR	iron (III) polymaltose	MAR*	

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
259	103896	Iron sucrose	USAN	iron (III) sucrose	USAN*	
260	95589	Isoamyl methoxycinnamate	ICID	amiloxate	INN	ü
261	54148	Isoascorbic acid	MI	erythorbic acid	USP	ü
262	92254	Isoceteth-20	ICID	isocetomacrogol 1000	ICID*	ü
263	89431	iso-Cyclocitral	PFC	isocyclocitral		ü
264	54200	Isopropyl adipate	PFC	diisopropyl adipate	MAR	ü
265	95457	Isopropyl hydroxybenzoate	ICID	isopropyl 4-hydroxybenzoate		
266	105760	Isopropyl PPG-2 isodeceth-7 carboxylate	ICID	isopropyl PPG-2 isodecomacrogol 350 carboxylate	ICID*	ü
267	89823	Lactobacillus kefir	IJFM	Lactobacillus kefir	LPSN	
268	54252	Lactose	BP	lactose monohydrate	BP*	ü
269	79271	Lactose anhydrous	BP	lactose	BP*	ü
270	94389	Laneth-5	ICID	lauromacrogol 250	ICID*	ü
271	105549	Lapatinib ditosylate monohydrate	USAN*	lapatinib ditosilate monohydrate		ü
272	94204	Laureth-10	ICID	lauromacrogol 500	INN*	ü
273	94230	Laureth-12	ICID	lauromacrogol 600	INN*	ü
274	104074	Laureth-2	ICID	lauromacrogol 100	INN*	ü
275	94231	Laureth-12.5	ICID	lauromacrogol 1150	INN*	ü
276	94225	Laureth-3	ICID	lauromacrogol 150	INN*	ü
277	94226	Laureth-4	ICID	lauromacrogol 200	INN*	ü
278	94227	Laureth-7	ICID	lauromacrogol 350	INN*	ü
279	94228	Laureth-8	ICID	lauromacrogol 400	INN*	ü
280	94229	Laureth-9	ICID	lauromacrogol 450	INN*	ü
281	61067	Lauryl diethanolamide	CAS	lauramide DEA		ü
282	105116	Lauryl PEG/PPG-18/18 Methicone	ICID	lauryl macrogol/PPG-900/18 meticone	ICID*	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
283	105945	Lauryl PEG-9 polydimethylsiloxyethyl dimeticone	ICID	lauryl macrogol 450 polydimethylsiloxyethyl dimeticone	ICID*	ü
284	89539	Laurylmethicone copolyol	ICID	laurylmethicone copolyol	ICID*	ü
285	54311	Lignocaine hydrochloride	BP	lidocaine hydrochloride monohydrate	BP*	ü
286	93311	Lignocaine hydrochloride anhydrous	BP	lidocaine hydrochloride	BAN	ü
287	94548	Lime	USP	calcium oxide		ü
288	54327	Lincomycin hydrochloride	BP	lincomycin hydrochloride monohydrate	BP*	ü
289	106236	Macrogol 6 glycerol caprylocaprate	EP	macrogol 300 glycerol caprylocaprate	EP*	ü
290	54382	Magnesium acetate	BP	magnesium acetate tetrahydrate		ü
291	54386	Magnesium aspartate	MAR	magnesium aspartate tetrahydrate	MAR*	ü
292	105258	Magnesium aspartate anhydrous	MAR	magnesium aspartate	BP*	ü
293	54388	Magnesium carbonate	USP	magnesium carbonate hydrate	USP*	ü
294	57943	Magnesium carbonate - heavy	BP	heavy magnesium carbonate		ü
295	58330	Magnesium carbonate - light	BP	light magnesium carbonate		ü
296	54389	Magnesium chloride	BP	magnesium chloride hexahydrate		ü
297	95409	Magnesium lactate	MAR	magnesium lactate dihydrate	BP	ü
298	54398	Magnesium phosphate	USP	magnesium phosphate pentahydrate	USP*	ü
299	92140	Magnesium phosphate - tribasic anhydrous	MI	magnesium phosphate - tribasic		ü
300	68917	Magnesium sulfate	BP	magnesium sulfate heptahydrate		ü
301	89305	Maldison	TGA	malathion	BP	ü
302	70177	Manganese aspartate	ICID	manganese (II) diaspartate	ICID*	
303	54416	Manganese chloride	USP	manganese (II) chloride tetrahydrate	USP*	
304	61598	Manganese gluconate	USP	manganese (II) gluconate	USP*	

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
305	54418	Manganese glycerophosphate	BPC	manganese (II) glycerophosphate	CAS	
306	66529	Manganese oxide	MI	manganese (II/III) oxide	MI*	
307	68918	Manganese sulfate	BP	manganese (II) sulphate tetrahydrate	BP*	
308	94872	Manganese sulfate monohydrate	BP	manganese (II) sulfate monohydrate	BP*	
309	54455	Meglumine diatrizoate	BP	diatrizoate meglumine	USP	ü
310	54460	Meglumine iothalamate	BP	iothalamate meglumine	USAN	ü
311	54461	Meglumine iotroxate	BAN	iotroxate meglumine	USAN	ü
312	54462	Meglumine ioxaglate	BAN	ioxaglate meglumine	USAN	ü
313	72290	Meglumine pentetate	BP	pentetate meglumine	TGA	ü
314	54475	Menthol	USP	racemic menthol	INN	ü
315	54478	Menthyl acetate	MI	L-menthyl acetate	BP*	ü
316	54495	Mercaptopurine	BP	mercaptopurine monohydrate		ü
317	81335	meta-Cresol	MI	metacresol	USAN	ü
318	61429	Methyl sulfide	MI	dimethyl sulfide		ü
319	54620	Methyldopa	BP	methyldopa sesquihydrate	BP*	ü
320	100645	Methyldopa anhydrous	BP	methyldopa	INN	ü
321	90411	Menthyl anthranilate	ICID	meradimate	INN	ü
322	104199	Methylene bis-benzotriazolyl tetramethylbutylphenol	ICID	bisotrizole	INN	ü
323	54707	Metoclopramide hydrochloride	BP	metoclopramide hydrochloride monohydrate	BP*	ü
324	90099	Metoclopramide hydrochloride anhydrous	BP	metoclopramide hydrochloride	CAS	ü
325	54732	Minocycline hydrochloride	BP	minocycline hydrochloride dihydrate		ü
326	77552	Monosodium glutamate	USP	monosodium glutamate monohydrate	USP*	ü
327	54763	Morphine hydrochloride	BP	morphine hydrochloride trihydrate	BP*	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
328	68482	Morphine sulfate	BP	morphine sulfate pentahydrate	BP*	ü
329	94770	Mussel - green lipped	MDF	green lipped mussel		ü
330	105508	N-(Methoxy-PEG-5000 carbamoyl)-dipalmitoylphosphatidylethanolamine sodium	TGA	n-(methoxy-macrogol 5000 carbamoyl)-dipalmitoylphosphatidylethanolamine sodium		ü
331	106577	Naloxone hydrochloride anhydrous	BP	naloxone hydrochloride	BAN	ü
332	54798	Naloxone hydrochloride	BP	naloxone hydrochloride dihydrate	BP*	ü
333	96621	Neopentyl glycol dicaprylate/dicaprate	ICID	neopentyl glycol dioctanoate/didecanoate	ICID*	ü
334	96954	Noneth-5	ICID	nonomacrogol 250	ICID*	ü
335	93223	Noradrenaline	BAN	norepinephrine	INN	ü
336	54907	Noradrenaline acid tartrate	BP	norepinephrine acid tartrate monohydrate	BP*	ü
337	54954	Octocrylene	USAN	octocrilene	INN	ü
338	54968	Octyl methoxycinnamate	ICID	octinoxate	INN	ü
339	54971	Octyl salicylate	ICID	octisalate	INN	ü
340	54972	Oestradiol	BAN	estradiol		ü
341	97672	Oestradiol hemihydrate	BAN	estradiol hemihydrate	BP	ü
342	54976	Oestradiol valerate	BAN	estradiol valerate		ü
343	54977	Oestrion	BAN	estriol		ü
344	54978	Estrogens - conjugated	USP	conjugated estrogens		ü
345	54979	Oestrone	BAN	estrone		ü
346	94246	Oestrone sulfate - sodium	USAN	estrone sulfate - sodium		ü
347	94220	Oleth-10	ICID	olomacrogol 500	ICID*	ü
348	94206	Oleth-3	ICID	olomacrogol 150	ICID*	ü
349	104297	Oleth-3 phosphate	ICID	olomacrogol 150 phosphate	ICID*	ü
350	94207	Oleth-5	ICID	olomacrogol 250	ICID*	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
351	94222	Oleth-8	ICID	olomacrogl 400	ICID*	ü
352	55030	Oxethazaine	BP	oxetacaine	INN	ü
353	55037	Oxpentifylline	BP	pentoxifylline	INN	ü
354	57963	Paraffin - soft white	BP	white soft paraffin		ü
355	73811	Paraffin - soft yellow	BP	yellow soft paraffin		ü
356	104206	PEG/PPG-18/18 dimethicone	ICID	macrogol/PPG-900/18 dimeticone	ICID*	ü
357	89479	PEG-10 soya sterol	ICID	macrogol 500 soya sterol	ICID*	ü
358	94276	PEG-10 stearate	ICID	macrogol 500 stearate	INN*	ü
359	94208	PEG-100 stearate	ICID	macrogol 5000 stearate	INN*	ü
360	93604	PEG-12 dilaurate	ICID	macrogol 600 dilaurate	ICID*	ü
361	80255	PEG-120 methyl glucose dioleate	ICID	macrogol 6000 methyl glucose dioleate	ICID*	ü
362	73763	PEG-15 cocamine	ICID	macrogol 750 cocamine	ICID*	ü
363	75948	PEG-150 distearate	ICID	macrogol 7500 distearate	ICID*	ü
364	104201	PEG-20 Almond glycerides	ICID	macrogol 1000 almond glycerides	ICID*	ü
365	96728	PEG-20 glyceryl oleate	ICID	macrogol 1000 glyceryl oleate	ICID*	ü
366	102737	PEG-20 Glyceryl stearate	ICID	macrogol 1000 glyceryl stearate	ICID*	ü
367	94067	PEG-20 methyl glucose sesquisteate	ICID	macrogol 1000 methyl glucose sesquisteate	ICID*	ü
368	94277	PEG-20 stearate	ICID	macrogol 1000 stearate	INN*	ü
369	93114	PEG-3 distearate	ICID	macrogol 150 distearate	ICID*	ü
370	97961	PEG-30 dipolyhydroxystearate	ICID	macrogol 1500 dipolyhydroxystearate	ICID*	ü
371	94278	PEG-30 stearate	ICID	macrogol 1500 stearate	INN*	ü
372	107517	PEG-32 stearate	ICID	macrogol 1600 stearate	INN*	ü
373	96046	PEG-35 castor oil	ICID	macrogol 1750 castor oil	ICID*	ü
374	91233	PEG-4 dilaurate	ICID	macrogol 200 dilaurate	ICID*	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
375	98740	PEG-4 Laurate	ICID	macrogol 200 laurate	INN*	ü
376	94282	PEG-4 stearate	ICID	macrogol 200 stearate	INN*	ü
377	96047	PEG-40 castor oil	ICID	macrogol 2000 castor oil	ICID*	ü
378	96048	PEG-40 hydrogenated castor oil	ICID	macrogol 2000 hydrogenated castor oil	ICID*	ü
379	60534	PEG-40 sorbitan peroleate	ICID	macrogol 2000 sorbitan peroleate	ICID*	ü
380	94280	PEG-40 stearate	ICID	macrogol 2000 stearate	INN*	ü
381	88351	PEG-5 glyceryl stearate	ICID	macrogol 250 glyceryl stearate	ICID*	ü
382	94831	PEG-50 stearate	ICID	macrogol 2500 stearate	INN*	ü
383	96852	PEG-55 propylene glycol oleate	ICID	macrogol 2750 propylene glycol oleate	ICID*	ü
384	92936	PEG-6 lauramide	ICID	macrogol 300 lauramide	ICID*	ü
385	107516	PEG-6 stearate	ICID	macrogol 300 stearate	INN*	ü
386	98176	PEG-60 Almond Glycerides	ICID	macrogol 3000 almond glycerides	ICID*	ü
387	95034	PEG-60 glyceryl isostearate	ICID	macrogol 3000 glyceryl isostearate	ICID*	ü
388	96370	PEG-60 hydrogenated castor oil	ICID	macrogol 3000 hydrogenated castor oil	ICID*	ü
389	96955	PEG-7 cocamide	ICID	macrogol 350 cocamide	ICID*	ü
390	89310	PEG-7 glyceryl cocoate	ICID	macrogol 350 glyceryl cocoate	ICID*	ü
391	96052	PEG-7 hydrogenated castor oil	ICID	macrogol 350 hydrogenated castor oil	ICID*	ü
392	94258	PEG-7 stearate	ICID	macrogol 350 stearate	INN*	ü
393	75949	PEG-75 lanolin	ICID	macrogol 3750 lanolin	ICID*	ü
394	104175	PEG-75 Stearate	ICID	macrogol 3750 stearate	INN*	ü
395	104571	PEG-8 behenate	ICID	macrogol 400 behenate	INN*	ü
396	105426	PEG-8 cetyl dimethicone	ICID	macrogol 400 cetyl dimethicone	ICID*	ü
397	98359	PEG-8 dilaurate	ICID	macrogol 400 dilaurate	ICID*	ü
398	91399	PEG-8 distearate	ICID	macrogol 400 distearate	ICID*	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
399	105870	PEG-8 laurate	ICID	macrogol 400 laurate	INN*	ü
400	92168	PEG-8 ricinoleate	ICID	macrogol 400 ricinoleate	ICID*	ü
401	60499	PEG-8 stearate	ICID	macrogol 400 stearate	INN*	ü
402	92755	Pentaerythrityl tetraoctanoate	ICID	pentaerythrityl tetralaurate		ü
403	55136	Pentamidine isethionate	BP	pentamidine isetionate		ü
404	55166	Pergolide mesylate	BAN	pergolide mesilate	BP	ü
405	55170	Pericyazine	BAN	periciazine	INN	ü
406	55214	Phenobarbitone	BP	phenobarbital	INN	ü
407	55215	Phenobarbitone sodium	BP	phenobarbital sodium	INN	ü
408	55234	Phentolamine mesylate	BP	phentolamine mesilate		ü
409	71558	Phenyl trimethicone	ICID	phenyl trimeticone		ü
410	90922	Phenylbenzimidazole sulfonic acid	ICID	enzulizole	INN	ü
411	56532	Phytic acid	MI	fytic acid	INN	ü
412	81933	Piperazine oestrone sulfate	MAR	estropipate	BP	ü
413	98644	Polyethylene glycol monomethyl ether	USP	macrogol monomethyl ether	USP*	ü
414	91937	Polystyrene sulfonate	USP	polystyrene sulfonate - hydrogen	USP*	ü
415	55421	Potassium acid tartrate	MAR	potassium hydrogen tartrate	BP	ü
416	55424	Potassium clorazepate	BAN	dipotassium clorazepate	BP	ü
417	104 49	PPG-1-PEG-9 lauryl glycol ether	ICID	PPG-1-macrogol 450 lauryl glycol ether	ICID*	ü
418	97054	PPG-5-ceteth-20	ICID	PPG-5-cetomacrogol 1000	ICID*	ü
419	94109	PPG-5-laureth-5	ICID	PPG-5-lauromacrogol 250	ICID*	ü
420	55461	Pralidoxime iodide	BAN	pralidoxime methiodide	INN	ü
421	99013	Pramipexole hydrochloride	BAN	pramipexole dihydrochloride	BP*	ü
422	106783	Pramipexole hydrochloride monohydrate	BAN	pramipexole dihydrochloride monohydrate	BP	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
423	55500	Procaine penicillin	BP	procaine benzylpenicillin		ü
424	55508	Prochlorperazine mesylate	BP	prochlorperazine mesilate		ü
425	104581	Propylene glycol dicaprates	ICID	propylene glycol didecanoate	ICID*	ü
426	73569	Propylene glycol dicaprylate/dicaprate	ICID	propylene glycol dioctanoate/didecanoate	ICID*	ü
427	91753	Propylene glycol isoceteth-3 acetate	ICID	propylene glycol isocetomacrogol 150 acetate	ICID*	ü
428	92183	PVP/VA Copolymer	ICID	copovidone		ü
429	77612	Quinine bisulfate	BP	quinine bisulfate heptahydrate	BP*	ü
430	82015	Quinine sulfate	BP	quinidine sulfate dihydrate	BP*	ü
431	102239	R,S- α Lipoic acid	CAS	alpha lipoic acid	USP	ü
432	68280	Retinyl acetate	BP	retinol acetate	INN*	ü
433	63235	Retinyl palmitate	BP	retinol palmitate	INN*	ü
434	55685	Rutin	MI	rutoside	INN	ü
435	55696	Salcatonin	BP	calcitonin (salmon)	INN	ü
436	55707	Samarium	MI	samarium (153Sm)	TGA	
437	96777	Saquinavir mesylate	BAN	saquinavir mesilate		ü
438	55783	Sodium calcium edetate	BP	sodium calcium edetate		ü
439	55785	Sodium carbonate anhydrous	BP	sodium carbonate	BP*	ü
440	90011	Sodium citrate anhydrous	BP	sodium citrate		ü
441	55101	Sodium diatrizoate	BP	sodium amidotrizoate		ü
442	88320	Sodium laureth sulfate	ICID	sodium lauromacrogol sulfate	ICID*	ü
443	96762	Sodium lauryl di(oxyethyl) sulfate	CAS	sodium lauril di(oxyethyl) sulfate		ü
444	68471	Sodium lauryl sulfate	BP	sodium lauril sulfate	BP*	ü
445	75660	Sodium lauryl sulfoacetate	ICID	sodium lauril sulfoacetate		ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
446	97536	Sodium methoxy PEG-40-carbonyl-distearoylphosphatidylethanolamine	TGA	sodium methoxy macrogol 2000-carbonyl-distearoylphosphatidylethanolamine	TGA	ü
447	90080	Sodium phosphate - dibasic anhydrous	USP	sodium phosphate - dibasic		ü
448	103327	Sodium phosphate - monobasic anhydrous	USP	sodium phosphate - monobasic	USP*	ü
449	55889	Sodium stearyl 2-lactylate	ICID	sodium stearyl lactylate		ü
450	69098	Sodium sulfate	BP	sodium sulfate decahydrate	BP*	ü
451	93372	Sodium sulfate anhydrous	BP	sodium sulfate	BP*	ü
452	93373	Sodium sulfite anhydrous	BP	sodium sulfite	BP*	ü
453	82070	Sodium thiosulfate	BP	sodium thiosulfate pentahydrate	BP*	ü
454	76323	Sodium trideceth sulfate	ICID	sodium tridecomacrogol sulfate	ICID*	ü
455	105481	Sorafenib tosylate	INN	sorafenib tosilate	USAN	ü
456	93417	Steareth-10	ICID	stearomacrogol 500	ICID*	ü
457	97791	Steareth-100	ICID	stearomacrogol 5000	ICID*	ü
458	93416	Steareth-2	ICID	stearomacrogol 100	ICID*	ü
459	92964	Steareth-20	ICID	stearomacrogol 1000	ICID*	ü
460	94405	Steareth-21	ICID	stearomacrogol 1050	ICID*	ü
461	74339	TFA-lauryl sulfate	ICID	trilamine lauryl sulfate	ICID*	ü
462	56087	Testosterone enanthate	BP	testosterone enantate		ü
463	56101	Tetracosactrin	BP	tetracosactide	INN	ü
464	56115	Tetrahydrozoline hydrochloride	BAN	tetryzoline hydrochloride	BP	ü
465	102869	Thiamine phosphate acid ester chloride dihydrate	MI	monophosphothiamine dihydrate	CAS	ü
466	89496	Thiamine phosphoric acid ester chloride	MI	monophosphothiamine	INN	ü
467	56159	Thioguanine	BP	tioguanine	INN	ü
468	89498	Triceteareth-4 phosphate	ICID	triceteareomacrogol 200 phosphate	ICID*	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
469	56275	Triethanolamine	BP	trolamine	INN	ü
470	74920	Triethanolamine lauryl sulfate	ICID	trolamine lauril sulfate	ICID*	ü
471	56279	Triethanolamine salicylate	ICID	trolamine salicylate	ICID*	ü
472	56288	Trimeprazine tartrate	BP	alimemazine tartrate		ü

Appendix 2: Prescription medicines active ingredients

Table 4: prescription medicine active ingredients proposed for harmonisation

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
1	58903	Actinomycin D	BAN	Dactinomycin		ü
2	51982	Adrenaline	BP	epinephrine	INN	ü
3	51983	Adrenaline acid tartrate	BP	epinephrine acid tartrate	BP*	ü
4	51985	Adrenaline hydrochloride	BP	epinephrine hydrochloride	BP*	ü
5	52059	Aluminium hydroxide	MI	hydrated aluminium hydroxide	BP*	ü
6	57910	Aluminium hydroxide - dried	BP	aluminium hydroxide		ü
7	52086	Amethocaine hydrochloride	BP	tetracaine hydrochloride		ü
8	52090	Amiloride hydrochloride	BP	amiloride hydrochloride dihydrate	BP*	ü
9	56667	Amlodipine besylate	BAN	amlodipine besilate		ü
10	56480	Amoxycillin	BP	amoxicillin		ü
11	60720	Amoxycillin sodium	BP	amoxicillin sodium		ü
12	52133	Amoxycillin trihydrate	BP	amoxicillin trihydrate		ü
13	52137	Amphotericin	BP	amphotericin B	INN	ü
14	52166	Amylobarbitone sodium	BP	amobarbital sodium		ü
15	95737	Apomorphine hydrochloride	BP	apomorphine hydrochloride hemihydrate	BP*	ü
16	52235	Atracurium besylate	BAN	atracurium besilate		ü
17	70757	Atropine sulfate	BP	atropine sulfate monohydrate	BP*	ü
18	96610	Bacillus Calmette and Guérin	BP	mycobacterium bovis (BCG strain)		
19	52278	Beclomethasone Dipropionate	BP	beclometasone dipropionate		ü
20	103481	Bee venom	HPUS	honey bee venom	AIN	
21	52304	Benzhexol hydrochloride	BP	trihexyphenidyl hydrochloride		ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
22	52320	Benztropine mesylate	BP	benzatropine mesilate		ü
23	52414	Bretylium tosylate	BAN	bretylium tosilate	BP	ü
24	52427	Bromocriptine mesylate	BP	bromocriptine mesilate		ü
25	52448	Bupivacaine hydrochloride	BP	bupivacaine hydrochloride monohydrate	BP*	ü
26	101754	Bupivacaine hydrochloride anhydrous	BP	bupivacaine hydrochloride		ü
27	52528	Calcium chloride	BP	Calcium chloride dihydrate		ü
28	52538	Calcium gluconate	BP	calcium gluconate monohydrate	BP*	ü
29	52614	Carbidopa	BP	carbidopa monohydrate	BP*	ü
30	52689	Cephalexin	BP	cefaalexin monohydrate		ü
31	100859	Cephalexin anhydrous	BP	cefaalexin		ü
32	52691	Cephalothin sodium	BP	cefaalotin sodium		ü
33	81269	Cephmandole	BAN	ceramandole	INN	ü
34	71817	Cephazolin	PAN	cefazolin		ü
35	52695	Cephazolin sodium	BAN	cefazolin sodium		ü
36	52793	Chlorthalidone	BP	chlortalidone		ü
37	52796	Cholecalciferol	BP	colecaciferol		ü
38	52798	Cholestyramine	BAN	colestyramine	INN	ü
39	94798	Chromic chloride	USP	chromium (III) chloride hexahydrate	USP*	ü
40	96377	Cisatracurium besylate	BAN	cisatracurium besilate		ü
41	97-39	Citric acid - anhydrous	BP	citric acid	BP*	ü
42	52917	Clomiphene citrate	BP	clomifene citrate		ü
43	52959	Codeine phosphate	BP	codeine phosphate hemihydrate		ü
44	52966	Colaspase	BAN	asparaginase	USAN	ü
45	93010	Co-methylcobalamin	MI	mecobalamin	INN	ü
46	58571	Cupric chloride dihydrate	MI	copper (II) chloride dihydrate	USP*	
47	94518	Cyanocobalamin(57Co)	BP	cyanocobalamin (57Co)	INN	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
48	53054	Cyclophosphamide	BP	cyclophosphamide monohydrate	INN*	ü
49	53057	Cyclosporin	BAN	ciclosporin		ü
50	97278	Cysteamine bitartrate	BAN	mercaptamine bitartrate		ü
51	53073	Dantrolene sodium	BAN	dantrolene sodium hemiheptahydrate	INN*	ü
52	97447	Delavirdine mesylate	USAN	delavirdine mesilate		ü
53	53110	Desferrioxamine mesylate	BP	desferrioxamine mesilate		ü
54	81377	Dexamphetamine sulfate	BP	dexamfetamine sulfate	BP*	ü
55	53146	Dextropropoxyphene napsylate	BP	dextropropoxyphene napsilate monohydrate		ü
56	53233	Dihydroergotamine mesylate	BP	dihydroergotamine mesilate		ü
57	104168	Dimeglumine gadobenate	BP	gadobenate dimeglumine	BP*	ü
58	72289	Dimeglumine gadopentetate	USAN	gadopentetate dimeglumine	USP*	ü
59	53329	Disodium etidronate	BAN	etidronate disodium	BP	ü
60	68222	Disodium pamidronate	PAN	pamidronate disodium	BP*	ü
61	97007	Dolasetron mesylate	BAN	dolasetron mesilate monohydrate	BAN*	ü
62	53367	Dothiepin hydrochloride	BP	dosulepin hydrochloride		ü
63	56553	Doxazosin mesylate	BAN	doxazosin mesilate	BP	ü
64	53373	Doxycycline hydrochloride	BP	doxycycline hyclate		ü
65	96966	Eformoterol	BAN	formoterol		ü
66	97220	Eformoterol fumarate	BAN	formoterol fumarate	BP*	ü
67	97221	Eformoterol fumarate dihydrate	BAN	formoterol fumarate dihydrate	BP	ü
68	97830	Eprosartan mesylate	BAN	eprosartan mesilate		ü
69	53458	Ethacrynic acid	BP	etacrynic acid		ü
70	53471	Ethinylestradiol	BP	ethinylestradiol		ü
71	107254	Ferric carboxymaltose	INN	iron(III) carboxymaltose	INN*	
72	59987	Flucloxacillin magnesium	BP	flucloxacillin magnesium octahydrate		ü
73	53651	Flucloxacillin sodium	BP	flucloxacillin sodium monohydrate	BP*	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
74	53662	Flumethasone pivalate	BAN	flumetasone pivalate	BP	ü
75	81511	Flupenthixol decanoate	BAN	flupentixol decanoate	BP	ü
76	90838	Flurbiprofen sodium	USP	flurbiprofen sodium dihydrate	USP*	ü
77	53730	Frusemide	BP	furosemide		ü
78	102321	Frusemide sodium	BP	furosemide sodium		ü
79	100588	Furosemide (Frusemide)	BP	furosemide		ü
80	53743	Fusidic acid	BP	fusidic acid hemihydrate	BP*	ü
81	94521	Gallium(67Ga) citrate	BP	gallium (67Ga) citrate	INN	ü
82	53790	Glucose	BP	glucose monohydrate	BP*	ü
83	58055	Glucose - anhydrous	BP	glucose	BP*	ü
84	53814	Glycopyrrolate	USP	glycopyrronium bromide	INN	ü
85	53856	Halethazole	BAN	halotazole	INN	ü
86	54017	Hydroxyurea	BP	hydroxycarbamide		ü
87	102968	Imatinib mesylate	INN	imatinib mesilate	INN*	ü
88	93243	Indium(111In) chloride	USAN	indium (111In) chloride	USP*	ü
89	94522	Indium(111In) hydroxyquinoline	BP	indium (111In) hydroxyquinoline	USP*	ü
90	94523	Indium(111In) pentetate	BP	indium (111In) pentetate	BP*	ü
91	54059	Indometacin	BP	indometacin		ü
92	54067	Insulin - human	BP	insulin		ü
93	104159	Iobenguane(123I) sulfate	USAN	iobenguane (123I) sulfate	USAN*	ü
94	96978	Ipratropium bromide	BP	ipratropium bromide monohydrate	INN*	ü
95	98828	Ipratropium bromide anhydrous	BP	ipratropium bromide	INN	ü
96	97484	Irinotecan hydrochloride	USAN	irinotecan hydrochloride trihydrate	USP	ü
97	69531	Iron polymaltose	MAR	iron (III) polymaltose	MAR*	
98	103896	Iron sucrose	USAN	iron (III) sucrose	USAN*	

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
99	105549	Lapatinib ditosylate monohydrate	USAN*	lapatinib ditosilate monohydrate		ü
100	94229	Laureth-9	ICID	lauromacrogol 450	INN*	ü
101	54311	Lignocaine hydrochloride	BP	lidocaine hydrochloride monohydrate	BP*	ü
102	93311	Lignocaine hydrochloride anhydrous	BP	lidocaine hydrochloride	BAN	ü
103	54327	Lincomycin hydrochloride	BP	lincomycin hydrochloride monohydrate	BP*	ü
104	54382	Magnesium acetate	BP	magnesium acetate tetrahydrate		ü
105	54389	Magnesium chloride	BP	magnesium chloride hexahydrate		ü
106	68917	Magnesium sulfate	BP	magnesium sulfate heptahydrate		ü
107	54416	Manganese chloride	USP	manganese (II) chloride tetrahydrate	USP*	
108	54455	Meglumine diatrizoate	BP	diatrizoate meglumine	USP	ü
109	54460	Meglumine iothalamate	BP	iothalamate meglumine	USAN	ü
110	54461	Meglumine iotroxate	BAN	iotroxate meglumine	USAN	ü
111	54462	Meglumine ioxaglate	BAN	ioxaglate meglumine	USAN	ü
112	54475	Menthol	USP	racementhol	INN	ü
113	54495	Mercaptopurine	BP	mercaptopurine monohydrate		ü
114	81335	meta-Cresol	MI	metacresol	USAN	ü
115	54620	Methy dopa	BP	methyldopa sesquihydrate	BP*	ü
116	54707	Metoclopramide hydrochloride	BP	metoclopramide hydrochloride monohydrate	BP*	ü
117	90099	Metoclopramide hydrochloride anhydrous	BP	metoclopramide hydrochloride	CAS	ü
118	54732	Minocycline hydrochloride	BP	minocycline hydrochloride dihydrate		ü
119	54763	Morphine hydrochloride	BP	morphine hydrochloride trihydrate	BP*	ü
120	68482	Morphine sulfate	BP	morphine sulfate pentahydrate	BP*	ü
121	54798	Naloxone hydrochloride	BP	naloxone hydrochloride dihydrate	BP*	ü
122	54907	Noradrenaline acid tartrate	BP	norepinephrine acid tartrate monohydrate	BP*	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
123	54972	Oestradiol	BAN	estradiol		ü
124	97672	Oestradiol hemihydrate	BAN	estradiol hemihydrate	BP	ü
125	54976	Oestradiol valerate	BAN	estradiol valerate		ü
126	54977	Oestriol	BAN	estriol		ü
127	54978	Oestrogens - conjugated	USP	conjugated estrogens		ü
128	55037	Oxpentifylline	BP	pentoxifylline	INN	ü
129	55136	Pentamidine isethionate	BP	pentamidine isetionate		ü
130	55166	Pergolide mesylate	BAN	pergolide mesilate	BP	ü
131	55170	Pericyazine	BAN	periciazine	INN	ü
132	55214	Phenobarbitone	BP	phenobarbital	INN	ü
133	55215	Phenobarbitone sodium	BP	phenobarbital sodium	INN	ü
134	55234	Phentolamine mesylate	BP	phentolamine mesilate		ü
135	56532	Phytic acid	MI	phytic acid	INN	ü
136	81933	Piperazine oestrone sulfate	MAR	estropipate	BP	ü
137	55434	Potassium clorazepate	BAN	dipotassium clorazepate	BP	ü
138	55461	Pralidoxime iodide	BAN	pralidoxime methiodide	INN	ü
139	99013	Pramipexole hydrochloride	BAN	pramipexole dihydrochloride	BP*	ü
140	106783	Pramipexole hydrochloride monohydrate	BAN	pramipexole dihydrochloride monohydrate	BP	ü
141	55500	Procaine penicillin	BP	procaine benzylpenicillin		ü
142	55508	Prochlorperazine mesylate	BP	prochlorperazine mesilate		ü
143	77012	Quinine bisulfate	BP	quinine bisulfate heptahydrate	BP*	ü
144	82015	Quinine sulfate	BP	quinidine sulfate dihydrate	BP*	ü
145	63235	Retinyl palmitate	BP	retinol palmitate	INN*	ü
146	55696	Salcatonin	BP	calcitonin (salmon)	INN	ü
147	55707	Samarium	MI	samarium (153Sm)	TGA	
148	96777	Saquinavir mesylate	BAN	saquinavir mesilate		ü
149	55801	Sodium diatrizoate	BP	sodium amidotrizoate		ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
150	82070	Sodium thiosulfate	BP	sodium thiosulfate pentahydrate	BP*	ü
151	105481	Sorafenib tosylate	INN	sorafenib tosilate	USAN	ü
152	56087	Testosterone enanthate	BP	testosterone enantate		ü
153	56101	Tetracosactrin	BP	tetracosactide	INN	ü
154	56159	Thioguanine	BP	tioguanine	INN	ü
155	56288	Trimeprazine tartrate	BP	alimemazine tartrate		ü

Appendix 3: Registered over-the-counter medicines active ingredients

Table 5: All OTC active ingredients proposed for harmonisation

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
1	90839	4-Methylbenzylidene camphor	ICID	enzacamene	INN	ü
2	51965	Acriflavine	MAR	acriflavinium chloride	INN	ü
3	51982	Adrenaline	BP	epinephrine	INN	ü
4	96313	Alpha tocopherol	BP	dl-alpha-tocopherol	USP*	
5	96314	Alpha tocopherol acetate	BP	dl-alpha-tocopheryl acetate	USP*	
6	57910	Aluminium hydroxide - dried	BP	aluminium hydroxide		ü
7	52063	Aluminium nitrate	MI	aluminium nitrate nonahydrate	BPAP*	ü
8	71128	Aluminium sulfate	BP	aluminium sulfate hydrated		ü
9	52091	Aminacrine hydrochloride	BAN	aminoacridine hydrochloride		ü
10	70757	Atropine sulfate	BP	atropine sulfate monohydrate	BP*	ü
11	52278	Beclomethasone Dipropionate	BP	beclometasone dipropionate		ü
12	52350	Berberine hydrochloride	MAR	berberine chloride	BPAP	ü
13	52467	Butoxyethyl nicotinate	MAR	nicoboxil	INN	ü
14	52473	Butyl aminobenzoate	USAN	butamben	USP	ü
15	95463	Butyl methoxydibenzoylmethane	ICID	avobenzene	INN	ü
16	52528	Calcium chloride	BP	Calcium chloride dihydrate		ü
17	52538	Calcium gluconate	BP	calcium gluconate monohydrate	BP*	ü
18	52543	Calcium hydrogen phosphate	BP	calcium hydrogen phosphate dihydrate	BP*	ü
19	63405	Calcium sulfate	BPAP	calcium sulfate hemihydrate	BPAP*	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
20	52739	Chlorbutol	BP	chlorobutanol hemihydrate	BP*	ü
21	52779	Chlorpheniramine maleate	BP	chlorphenamine maleate		ü
22	52796	Cholecalciferol	BP	colecalfiferol		ü
23	97439	Citric acid - anhydrous	BP	citric acid	BP*	ü
24	52959	Codeine phosphate	BP	codeine phosphate hemihydrate		ü
25	94807	Cupric sulfate monohydrate	MI	copper (II) sulfate monohydrate	MI*	
26	94810	Cupric sulfate pentahydrate	MI	copper (II) sulfate pentahydrate	USP*	
27	53063	Cyproheptadine hydrochloride	BP	cyproheptadine hydrochloride sesquihydrate	BP*	ü
28	53142	Dextromethorphan hydrobromide	BP	dextromethorphan hydrobromide monohydrate	BP*	ü
29	91312	Diclofenac diethylammonium	BAN	diclofenac diethylamine	BP	ü
30	64435	Dimethicone 350	BP	dimethicone 350	BP*	ü
31	81428	Diphemanil methylsulfate	BAN	diphemanil metilsulfate	INN	ü
32	93271	dl-alpha tocopheryl acetate	BP	dl-alpha-tocopheryl acetate	USP*	
33	53539	Ethylmorphine hydrochloride	BP	ethylmorphine hydrochloride dihydrate	BP*	ü
34	94793	Ferric ammonium citrate	MAR	iron (III) ammonium citrate	USP*	
35	53619	Ferric glycerophosphate	USAN	iron (III) glycerophosphate	USAN*	
36	53631	Ferrous fumarate	BP	iron (II) fumarate	BP*	
37	53632	Ferrous gluconate	BP	iron (II) gluconate	BP*	
38	53635	Ferrous phosphate	MAR	iron (II) phosphate octahydrate	MI*	
39	61280	Ferrous sulfate	BP	iron (II) sulfate heptahydrate	BP*	
40	60856	Ferrous sulfate - dried	BP	iron (II) sulfate	BP*	
41	53790	Glucose	BP	glucose monohydrate	BP*	ü
42	58055	Glucose - anhydrous	BP	glucose	BP*	ü
43	53795	Glutaraldehyde	BP	glutaral	INN	ü
44	53813	Glycol salicylate	MAR	hydroxyethyl salicylate	BP	ü
45	53839	Guaiphenesin	BP	guaifenesin	INN	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
46	93288	Heparinoid	MAR	heparinoids		ü
47	53892	Hexachlorophane	BP	hexachlorophene		ü
48	53899	Hexamidine isethionate	MAR	hexamidine isoetionate		ü
49	53903	Hexamine hippurate	BAN	methenamine hippurate		ü
50	81585	Hydroxyethylrutosides	MAR	oxerutins	BAN	ü
51	81590	Hydroxyquinoline sulfate	MAR	oxyquinoline sulfate	USP	ü
52	75213	Hyoscyamine sulfate	BP	hyoscyamine sulfate dihydrate	BP*	ü
53	54059	Indomethacin	BP	indometacin		ü
54	96978	Ipratropium bromide	BP	ipratropium bromide monohydrate	INN*	ü
55	98828	Ipratropium bromide anhydrous	BP	ipratropium bromide	INN	ü
56	69531	Iron polymaltose	MAR	iron (III) polymaltose	MAR*	
57	94229	Laureth-9	ICID	lauro macrogol 450	INN*	ü
58	54311	Lignocaine hydrochloride	BP	lidocaine hydrochloride monohydrate	BP*	ü
59	93311	Lignocaine hydrochloride anhydrous	BP	lidocaine hydrochloride	BAN	ü
60	54386	Magnesium aspartate	MAR	magnesium aspartate tetrahydrate	MAR*	ü
61	54388	Magnesium carbonate	USP	magnesium carbonate hydrate	USP*	ü
62	57943	Magnesium carbonate - heavy	BP	heavy magnesium carbonate		ü
63	58330	Magnesium carbonate - light	BP	light magnesium carbonate		ü
64	54389	Magnesium chloride	BP	magnesium chloride hexahydrate		ü
65	54393	Magnesium phosphate	USP	magnesium phosphate pentahydrate	USP*	ü
66	60917	Magnesium sulfate	BP	magnesium sulfate heptahydrate		ü
67	89305	Maldison	TGA	malathion	BP	ü
68	61598	Manganese gluconate	USP	manganese (II) gluconate	USP*	
69	54418	Manganese glycerophosphate	BPC	manganese (II) glycerophosphate	CAS	
70	68918	Manganese sulfate	BP	manganese (II) sulphate tetrahydrate	BP*	

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
71	94872	Manganese sulfate monohydrate	BP	manganese (II) sulfate monohydrate	BP*	
72	54475	Menthol	USP	racementhol	INN	ü
73	54707	Metoclopramide hydrochloride	BP	metoclopramide hydrochloride monohydrate	BP*	ü
74	94770	Mussel - green lipped	MDF	green lipped mussel		ü
75	54968	Octyl methoxycinnamate	ICID	octinoxate	INN	ü
76	57963	Paraffin - soft white	BP	white soft paraffin		ü
77	68280	Retinyl acetate	BP	retinol acetate	INN*	ü
78	63235	Retinyl palmitate	BP	retinol palmitate	INN*	ü
79	55685	Rutin	MI	rutoside	INN	ü
80	55785	Sodium carbonate anhydrous	BP	sodium carbonate	BP*	ü
81	90041	Sodium citrate anhydrous	BP	sodium citrate		ü
82	55801	Sodium diatrizoate	BP	sodium amidotrizoate		ü
83	75660	Sodium lauryl sulfoacetate	ICID	sodium lauryl sulfoacetate		ü
84	90080	Sodium phosphate - dibasic anhydrous	USP	sodium phosphate - dibasic		ü
85	69098	Sodium sulfate	BP	sodium sulfate decahydrate	BP*	ü
86	93372	Sodium sulfate anhydrous	BP	sodium sulfate	BP*	ü
87	56115	Tetrahydrozoline hydrochloride	BAN	tetryzoline hydrochloride	BP	ü
88	74920	Triethanolamine lauryl sulfate	ICID	trolamine lauryl sulfate	ICID*	ü
89	56279	Triethanolamine salicylate	ICID	trolamine salicylate	ICID*	ü
90	51288	Trimeprazine tartrate	BP	alimemazine tartrate		ü

Appendix 4: Sunscreen active ingredients

Table 6: All sunscreen ingredients proposed for harmonisation

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
1	90839	4-Methylbenzylidene camphor	ICID	enzacamene	INN	ü
2	95463	Butyl methoxydibenzoylmethane	ICID	avobenzene	INN	ü
3	95589	Isoamyl methoxycinnamate	ICID	amiloxate	INN	ü
4	90411	Menthyl anthranilate	ICID	merad mat	INN	ü
5	104199	Methylene bis-benzotriazolyl tetramethylbutylphenol	ICID	bisotrizole	INN	ü
6	54954	Octocrylene	USAN	octocrilene	INN	ü
7	54968	Octyl methoxycinnamate	ICID	octinoxate	INN	ü
8	54971	Octyl salicylate	ICID	octisalate	USP	ü
9	84708	Octyl triazone	ICID	ethylhexyl triazone		ü
10	56279	Triethanolamine salicylate	ICID	trolamine salicylate	ICID*	ü

Appendix 5: Registered complementary medicines active ingredients

Table 7: All Registered complementary active ingredients proposed for harmonisation

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
1	52543	Calcium hydrogen phosphate	BP	calcium hydrogen phosphate dihydrate	BP*	ü
2	95202	Calcium hydrogen phosphate anhydrous	BP	calcium hydrogen phosphate	BP*	ü
3	52796	Cholecalciferol	BP	colecalfiferol		ü
4	94798	Chromic chloride	USP	chromium (III) chloride hexahydrate	USP*	
5	94803	Cupric oxide	MI	copper (II) oxide	MI*	
6	94806	Cupric sulfate anhydrous	MI	copper (II) sulfate	MI*	
7	53624	Ferric pyrophosphate	MI	iron (III) pyrophosphate	MI*	
8	53631	Ferrous fumarate	BP	iron (II) fumarate	BP*	
9	69280	Ferrous sulfate	BP	iron (II) sulfate heptahydrate	BP*	
10	68856	Ferrous sulfate - dried	BP	iron (II) sulfate	BP*	
11	54388	Magnesium carbonate	USP	magnesium carbonate hydrate	USP*	ü
12	58330	Magnesium carbonate - light	BP	light magnesium carbonate		ü
13	54396	Magnesium phosphate	USP	magnesium phosphate pentahydrate	USP*	ü
14	94872	Manganese sulfate monohydrate	BP	manganese (II) sulfate monohydrate	BP*	
15	68280	Retinyl acetate	BP	retinol acetate	INN*	ü
16	63235	Retinyl palmitate	BP	retinol palmitate	INN*	ü
17	90080	Sodium phosphate - dibasic anhydrous	USP	sodium phosphate - dibasic		ü
18	69098	Sodium sulfate	BP	sodium sulfate decahydrate	BP*	ü
19	93372	Sodium sulfate anhydrous	BP	sodium sulfate	BP*	ü

Appendix 6: Listed medicines active ingredients

Table 8: All listed medicine active ingredients proposed for harmonisation

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
1	90839	4-Methylbenzylidene camphor	ICID	enzacamene	INN	ü
2	96313	Alpha tocopherol	BP	dl-alpha-tocopherol	USP*	
3	96314	Alpha tocopherol acetate	BP	dl-alpha-tocopheryl acetate	USP*	
4	52047	Alum	BP	alum dodecahydrate	BP*	ü
5	52206	Antimony potassium tartrate	USP	antimony potassium tartrate trihydrate	USP*	ü
6	95337	Apomorphine hydrochloride	BP	apomorphine hydrochloride hemihydrate	BP*	ü
7	94769	Bee	AIN	honey bee	HPUS	
8	95463	Butyl methoxydibenzoylmethane	ICID	avobenzone	INN	ü
9	97719	Calcium citrate hydrate	MI	calcium citrate tetrahydrate	USAN*	ü
10	52538	Calcium gluconate	BP	calcium gluconate monohydrate	BP*	ü
11	52543	Calcium hydrogen phosphate	BP	calcium hydrogen phosphate dihydrate	BP*	ü
12	95202	Calcium hydrogen phosphate anhydrous	BP	calcium hydrogen phosphate	BP*	ü
13	100565	Calcium lactate anhydrous	BP	calcium lactate	BP*	ü
14	13405	Calcium sulfate	BPAP	calcium sulfate hemihydrate	BPAP*	ü
15	93554	Chitosan	ICID	poliglusam	INN	ü
16	52796	Cholecalciferol	BP	colecalfiferol		ü
17	94798	Chromic chloride	USP	chromium (III) chloride hexahydrate	USP*	ü
18	97439	Citric acid - anhydrous	BP	citric acid	BP*	ü
19	94938	Cupric acetate monohydrate	MI	copper (II) acetate monohydrate	MI*	
20	100063	Cupric citrate	MI	copper (II) citrate	MI*	

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
21	104902	Cupric citrate hemipentahydrate	MI	copper (II) citrate hemipentahydrate	MI*	
22	94803	Cupric oxide	MI	copper (II) oxide	MI*	
23	94806	Cupric sulfate anhydrous	MI	copper (II) sulfate	MI*	
24	94807	Cupric sulfate monohydrate	MI	copper (II) sulfate monohydrate	MI*	
25	94810	Cupric sulfate pentahydrate	MI	copper (II) sulfate pentahydrate	USP*	
26	93271	dl-alpha tocopheryl acetate	BP	dl-alpha-tocopheryl acetate	USP*	
27	60075	Docosahexaenoic acid	MAR	doconexent	INN	ü
28	53393	Eicosapentaenoic acid	MI	icosapent	INN	ü
29	94819	Ferric chloride hexahydrate	MAR	iron(III) chloride hexahydrate	BP	
30	53623	Ferric phosphate	MI	iron (III) phosphate	MI*	
31	53624	Ferric pyrophosphate	MI	iron (III) pyrophosphate	MI*	
32	93577	Ferrosoferric phosphate	HPUS	iron phosphate		
33	53631	Ferrous fumarate	BP	iron (II) fumarate	BP*	
34	53632	Ferrous gluconate	BP	iron (II) gluconate	BP*	
35	98671	Ferrous gluconate dihydrate	BP	iron (II) gluconate dihydrate	BP*	
36	93576	Ferrous iodide	MI	iron (II) iodide	MI*	
37	53633	Ferrous lactate	MAR	iron (II) lactate trihydrate	MAR*	
38	53635	Ferrous phosphate	MAR	iron (II) phosphate octahydrate	MI*	
39	69280	Ferrous sulfate	BP	iron (II) sulfate heptahydrate	BP*	
40	68850	Ferrous sulfate - dried	BP	iron (II) sulfate	BP*	
41	101812	Glucosamine sulfate-potassium chloride complex	TGA	glucosamine sulfate potassium chloride	USP	ü
42	101813	Glucosamine sulfate-sodium chloride complex	TGA	glucosamine sulfate sodium chloride	USP	ü
43	53790	Glucose	BP	glucose monohydrate	BP*	ü
44	58055	Glucose - anhydrous	BP	glucose	BP*	ü
45	95589	Isoamyl methoxycinnamate	ICID	amiloxate	INN	ü
46	89823	Lactobacillus kefir	IJFM	Lactobacillus kefir	LPSN	

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
47	54386	Magnesium aspartate	MAR	magnesium aspartate tetrahydrate	MAR*	ü
48	105258	Magnesium aspartate anhydrous	MAR	magnesium aspartate	BP*	ü
49	54388	Magnesium carbonate	USP	magnesium carbonate hydrate	USP*	ü
50	57943	Magnesium carbonate - heavy	BP	heavy magnesium carbonate		ü
51	58330	Magnesium carbonate - light	BP	light magnesium carbonate		ü
52	54389	Magnesium chloride	BP	magnesium chloride hexahydrate		ü
53	54398	Magnesium phosphate	USP	magnesium phosphate pentahydrate	USP*	ü
54	92140	Magnesium phosphate - tribasic anhydrous	MI	magnesium phosphate - tribasic		ü
55	68917	Magnesium sulfate	BP	magnesium sulfate heptahydrate		ü
56	70177	Manganese aspartate	ICID	manganese (II) diaspertate	ICID*	
57	54416	Manganese chloride	USP	manganese (II) chloride tetrahydrate	USP*	
58	61598	Manganese gluconate	USP	manganese (II) gluconate	USP*	
59	66529	Manganese oxide	MI	manganese (II/III) oxide	MI*	
60	68918	Manganese sulfate	BP	manganese (II) sulphate tetrahydrate	BP*	
61	94872	Manganese sulfate monohydrate	BP	manganese (II) sulfate monohydrate	BP*	
62	54475	Menthol	USP	racementhol	INN	ü
63	90411	Menthyl aminosalicylate	ICID	meradimate	INN	ü
64	104199	Methylene bis-benzotriazolyl tetramethylbutylphenol	ICID	bisoctrizole	INN	ü
65	54771	Mussel - green lipped	MDF	green lipped mussel		ü
66	54954	Octocrylene	USAN	octocrilene	INN	ü
67	54968	Octyl methoxycinnamate	ICID	octinoxate	INN	ü
68	54971	Octyl salicylate	ICID	octisalate	INN	ü
69	54979	Oestrone	BAN	estrone		ü
70	90922	Phenylbenzimidazole sulfonic acid	ICID	ensulizole	INN	ü
71	94109	PPG-5-laureth-5	ICID	PPG-5-lauromacrogol 250	ICID*	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
72	102239	R,S-alpha Lipoic acid	CAS	alpha lipoic acid	USP	ü
73	68280	Retinyl acetate	BP	retinol acetate	INN*	ü
74	63235	Retinyl palmitate	BP	retinol palmitate	INN*	ü
75	55685	Rutin	MI	rutoside	INN	ü
76	90080	Sodium phosphate - dibasic anhydrous	USP	sodium phosphate - dibasic		ü
77	69098	Sodium sulfate	BP	sodium sulfate decahydrate	BP*	ü
78	93372	Sodium sulfate anhydrous	BP	sodium sulfate	BP*	ü
79	102869	Thiamine phosphate acid ester chloride dihydrate	MI	monophosphothiamine dihydrate	CAS	ü
80	89496	Thiamine phosphoric acid ester chloride	MI	monophosphothiamine	INN	ü

Appendix 7: ABNs

Table 9: All ABNs proposed for harmonisation

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
1	96610	Bacillus Calmette and Guerin	BP	Mycobacterium bovis (BCG strain)		
2	94769	Bee	AIN	honey bee	HPUS	
3	103481	Bee venom	HPUS	honey bee venom	AIN	
4	54067	Insulin - human	BP	insulin		ü
5	89823	Lactobacillus kefir	IJFM	Lactobacillus kefir	LPSN	
6	94770	Mussel - green lipped	MDF	green lipped mussel		

Appendix 8: Export Only medicines active ingredients

Table 10: All Export Only medicines active ingredients proposed for harmonisation

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
1	90839	4-Methylbenzylidene camphor	ICID	enzacamene	INN	ü
2	51982	Adrenaline	BP	epinephrine	INN	ü
3	51983	Adrenaline acid tartrate	BP	epinephrine acid tartrate	BP*	ü
4	52047	Alum	BP	alum dodecahydrate	BP*	ü
5	52059	Aluminium hydroxide	MI	hydrated aluminium hydroxide	BP*	ü
6	57910	Aluminium hydroxide - dried	BP	aluminium hydroxide		ü
7	71128	Aluminium sulfate	BP	aluminium sulfate hydrated		ü
8	52090	Amiloride hydrochloride	BP	amiloride hydrochloride dihydrate	BP*	ü
9	52133	Amoxycillin trihydrate	BP	amoxicillin trihydrate		ü
10	52235	Atracurium besylate	BAN	atracurium besilate		ü
11	70757	Atropine sulfate	BP	atropine sulfate monohydrate	BP*	ü
12	96610	Bacillus Calmette and Guérin	BP	Mycobacterium bovis (BCG strain)		
13	52278	Beclomethasone Dipropionate	BP	beclometasone dipropionate		ü
14	52427	Bromocriptine mesylate	BP	bromocriptine mesilate		ü
15	52448	Bupivacaine hydrochloride	BP	bupivacaine hydrochloride monohydrate	BP*	ü
16	95463	Butyl methoxydibenzoylmethane	ICID	avobenzone	INN	ü
17	52528	Calcium chloride	BP	Calcium chloride dihydrate		ü
18	52538	Calcium gluconate	BP	calcium gluconate monohydrate	BP*	ü
19	52543	Calcium hydrogen phosphate	BP	calcium hydrogen phosphate dihydrate	BP*	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
20	95202	Calcium hydrogen phosphate anhydrous	BP	calcium hydrogen phosphate	BP*	ü
21	63405	Calcium sulfate	BPAP	calcium sulfate hemihydrate	BPAP*	ü
22	52614	Carbidopa	BP	carbidopa monohydrate	BP*	ü
23	87613	Carbidopa anhydrous	BP	carbidopa	INN	ü
24	99554	Chitosan	ICID	poliglusam	INN	ü
25	52739	Chlorbutol	BP	chlorobutanol hemihydrate	BP*	ü
26	52779	Chlorpheniramine maleate	BP	chlorphenamine maleate		ü
27	52796	Cholecalciferol	BP	colecalfiferol		ü
28	52798	Cholestyramine	BAN	colestyramine	INN	ü
29	94798	Chromic chloride	USP	chromium (III) chloride hexahydrate	USP*	ü
30	97439	Citric acid - anhydrous	BP	citric acid	BP*	ü
31	52959	Codeine phosphate	BP	codeine phosphate hemihydrate		ü
32	52966	Colaspase	BAN	asparaginase	USAN	ü
33	94811	Crystal violet CI42555	MAR	methylosanilinium chloride	INN	ü
34	58571	Cupric chloride dihydrate	MI	copper (II) chloride dihydrate	USP*	
35	94803	Cupric oxide	MI	copper (II) oxide	MI*	
36	94806	Cupric sulfate anhydrous	MI	copper (II) sulfate	MI*	
37	94810	Cupric sulfate pentahydrate	MI	copper (II) sulfate pentahydrate	USP*	
38	53063	Cyproheptadine hydrochloride	BP	cyproheptadine hydrochloride sesquihydrate	BP*	ü
39	53110	Desferrioxamine mesylate	BP	desferrioxamine mesilate		ü
40	53142	Dextromethorphan hydrobromide	BP	dextromethorphan hydrobromide monohydrate	BP*	Y
41	53248	Di-iodohydroxyquinoline	BAN	diiodohydroxyquinoline	INN	ü
42	53329	Disodium etidronate	BAN	etidronate disodium	BP	ü
43	68222	Disodium pamidronate	BAN	pamidronate disodium	BP*	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
44	93271	dl-alpha tocopheryl acetate	BP	dl-alpha-tocopheryl acetate	USP*	
45	60075	Docosahexaenoic acid	MAR	doconexent	INN	ü
46	53367	Dothiepin hydrochloride	BP	dosulepin hydrochloride		ü
47	53373	Doxycycline hydrochloride	BP	doxycycline hyclate		ü
48	53393	Eicosapentaenoic acid	MI	icosapent	INN	ü
49	53471	Ethinylestradiol	BP	ethinylestradiol		ü
50	53565	Ethinodiol diacetate	BP	etynodiol diacetate		ü
51	94819	Ferric chloride hexahydrate	MAR	iron(III) chloride hexahydrate	BP	
52	53624	Ferric pyrophosphate	MI	iron (III) pyrophosphate	MI*	
53	53631	Ferrous fumarate	BP	iron (II) fumarate	BP*	
54	53632	Ferrous gluconate	BP	iron (II) gluconate	BP*	
55	98671	Ferrous gluconate dihydrate	BP	iron (II) gluconate dihydrate	BP*	
56	69280	Ferrous sulfate	BP	iron (II) sulfate heptahydrate	BP*	
57	68856	Ferrous sulfate - dried	BP	iron (II) sulfate	BP*	
58	53730	Frusemide	BP	furosemide		ü
59	101812	Glucosamine sulfate-potassium chloride complex	TGA	glucosamine sulfate potassium chloride	USP	ü
60	101813	Glucosamine sulfate-sodium chloride complex	TGA	glucosamine sulfate sodium chloride	USP	ü
61	53790	Glucose	BP	glucose monohydrate	BP*	ü
62	58055	Glucose - anhydrous	BP	glucose	BP*	ü
63	53839	Guaiphenesin	BP	guaifenesin	INN	ü
64	93306	Haematoporphyrin	MAR	hematoporphyrin	MI	ü
65	95160	Haematoporphyrin dihydrochloride	MAR	hematoporphyrin dihydrochloride	MI*	ü
66	53903	Hexamine hippurate	BAN	methenamine hippurate		ü
67	54059	Indomethacin	BP	indometacin		ü
68	56468	Indomethacin sodium	USP	indometacin sodium trihydrate	INN*	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
69	94069	Iodobenzylguanidine(131I) sulfate	USAN	iobenguane (131I) sulfate		ü
70	97484	Irinotecan hydrochloride	USAN	irinotecan hydrochloride trihydrate	USP	ü
71	103896	Iron sucrose	USAN	iron (III) sucrose	USAN*	
72	95589	Isoamyl methoxycinnamate	ICID	amiloxate	INN	ü
73	54252	Lactose	BP	lactose monohydrate	BP*	ü
74	54311	Lignocaine hydrochloride	BP	lidocaine hydrochloride monohydrate	BP*	ü
75	93311	Lignocaine hydrochloride anhydrous	BP	lidocaine hydrochloride	BAN	ü
76	54382	Magnesium acetate	BP	magnesium acetate tetrahydrate		ü
77	54386	Magnesium aspartate	MAR	magnesium aspartate tetrahydrate	MAR*	ü
78	57943	Magnesium carbonate - heavy	BP	heavy magnesium carbonate		ü
79	54389	Magnesium chloride	BP	magnesium chloride hexahydrate		ü
80	95409	Magnesium lactate	MAR	magnesium lactate dihydrate	BP	ü
81	54398	Magnesium phosphate	USP	magnesium phosphate pentahydrate	USP*	ü
82	92140	Magnesium phosphate - tribasic anhydrous	MI	magnesium phosphate - tribasic		
83	68917	Magnesium sulfate	BP	magnesium sulfate heptahydrate		ü
84	54416	Manganese chloride	USP	manganese (II) chloride tetrahydrate	USP*	
85	61533	Manganese gluconate	USP	manganese (II) gluconate	USP*	
86	58918	Manganese sulfate	BP	manganese (II) sulphate tetrahydrate	BP*	
87	94872	Manganese sulfate monohydrate	BP	manganese (II) sulfate monohydrate	BP*	
88	54475	Menthol	USP	racementhol	INN	ü
89	54620	Methyldopa	BP	methyldopa sesquihydrate	BP*	ü
90	100645	Methyldopa anhydrous	BP	methyldopa	INN	ü
91	104199	Methylene bis-benzotriazolyl tetramethylbutylphenol	ICID	bisotrizole	INN	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
92	54707	Metoclopramide hydrochloride	BP	metoclopramide hydrochloride monohydrate	BP*	ü
93	54732	Minocycline hydrochloride	BP	minocycline hydrochloride dihydrate		ü
94	54763	Morphine hydrochloride	BP	morphine hydrochloride trihydrate	BP*	ü
95	68482	Morphine sulfate	BP	morphine sulfate pentahydrate	BP*	ü
96	94770	Mussel - green lipped	MDF	green lipped mussel		ü
97	54798	Naloxone hydrochloride	BP	naloxone hydrochloride dihydrate	BP*	ü
98	54907	Noradrenaline acid tartrate	BP	norepinephrine acid tartrate monohydrate	BP*	ü
99	54954	Octocrylene	USAN	octocrilene	INN	ü
100	54968	Octyl methoxycinnamate	ICID	octinoxate	INN	ü
101	54971	Octyl salicylate	ICID	octisalate	INN	ü
102	54972	Oestradiol	BAN	estradiol		ü
103	54978	Oestrogens - conjugated	USP	conjugated estrogens		ü
104	55030	Oxethazaine	BP	oxetacaine	INN	ü
105	55136	Pentamidine isethionate	BP	pentamidine isetionate		ü
106	90922	Phenylbenzimidazole sulfonic acid	ICID	ensulizole	INN	ü
107	55508	Prochlorperazine mesylate	BP	prochlorperazine mesilate		ü
108	77612	Quinine bisulfate	BP	quinine bisulfate heptahydrate	BP*	ü
109	82015	Quinine sulfate	BP	quinidine sulfate dihydrate	BP*	ü
110	102239	R,S-alpha Lipoic acid	CAS	alpha lipoic acid	USP	ü
111	68280	Retinyl acetate	BP	retinol acetate	INN*	ü
112	63235	Retinyl palmitate	BP	retinol palmitate	INN*	ü
113	55685	Rutin	MI	rutoside	INN	ü
114	90080	Sodium phosphate - dibasic anhydrous	USP	sodium phosphate - dibasic		ü
115	69098	Sodium sulfate	BP	sodium sulfate decahydrate	BP*	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Meets INN Policy?
116	82070	Sodium thiosulfate	BP	sodium thiosulfate pentahydrate	BP*	ü
117	56279	Triethanolamine salicylate	ICID	trolamine salicylate	ICID*	ü
118	56288	Trimeprazine tartrate	BP	alimemazine tartrate		ü

Appendix 9: Excipient ingredients

Table 11: All excipients proposed for harmonisation

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Prescription Only	Export Only	Listed	Registered comp.	Over the counter	Meets INN Policy?
1	53999	2-hydroxymethylfuran	MI	furfuryl alcohol				ü			ü
2	81918	3-phenyl propyl alcohol	PFC	phenylpropanol	USAN		ü	ü		ü	ü
3	90839	4-Methylbenzylidene camphor	ICID	enzacamene	INN			ü			ü
4	51951	6-acetyl-1,1,3,4,4,6-hexamethyl tetrahydronaphthalene	PFC	7-acetyl-1,1,3,4,4,6-hexamethyl tetrahydronaphthalene			ü	ü		ü	
5	54012	8-hydroxyquinoline	MI	oxyquinoline	USAN	ü					ü
6	103505	Acrylates/steareth-20 methacrylate copolymer	ICID	acrylates/stearomacrogol 1000 methacrylate copolymer	ICID*		ü	ü			ü
7	93569	Alizarin cyanine green F	MI	acid green 25	CI			ü			
8	52016	Allylamyl glycolate	CAS	allyl amyl glycolate	TGA		ü	ü		ü	ü
9	96313	Alpha tocopherol	BP	dl-alpha-tocopherol	USP*	ü	ü	ü		ü	
10	96314	Alpha tocopherol acetate	BP	dl-alpha-tocopheryl acetate	USP*		ü	ü			
11	80265	alpha-iso-Methyl ionone	PFC	alfa-iso-methyl ionone	PFC*		ü	ü		ü	
12	52047	Alum	BP	alum dodecahydrate	BP*	ü		ü		ü	ü
13	52059	Aluminium hydroxide	MI	hydrated aluminium hydroxide	BP*	ü	ü	ü		ü	ü
14	57910	Aluminium hydroxide - dried	BP	aluminium hydroxide		ü	ü	ü		ü	ü
15	88051	Aluminium oxide anhydrous	MI	aluminium oxide				ü			ü
16	106994	Ammonium acryloyldimethyltaurate /steareth-8	ICID	ammonium acryloyldimethyltaurate/stearomacrogol 400 methacrylate	ICID*			ü			ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Prescription	Export Only	Listed	Registered comp. Over the counter	Meets INN Policy?
		methacrylate copolymer		copolymer						
17	52122	Ammonium hydroxide	MAR	strong ammonia solution/dilute ammonia solution	BP	ü	ü	ü	ü	ü
18	89500	Ammonium laureth sulfate	ICID	ammonium lauromacrogol sulfate	ICID*		ü	ü		ü
19	81128	Ammonium lauryl sulfate	ICID	ammonium lauril sulfate			ü	ü		ü
20	52206	Antimony potassium tartrate	USP	antimony potassium tartrate trihydrate	USP*	ü				ü
21	90093	Apricot kernel oil PEG-6 esters	ICID	apricot kernel oil macrogol 300 esters	ICID*			ü		ü
22	106112	Behenoyl polyoxyglycerides	TGA	behenoyl macrogolglycerides	USP*	ü				ü
23	52309	Benzodihydropyrone	FCC	dihydrocoumarin		ü		ü		ü
24	103937	Bis-peg-12 dimethicone beeswax	ICID	macrogol 600 dimeticone beeswax	ICID*			ü		ü
25	95463	Butyl methoxydibenzoylmethane	ICID	avobenzene	INN			ü		ü
26	93476	C12-15 alkyl benzoate	ICID	alkyl (C12-15) benzoate	USP		ü	ü		ü
27	52528	Calcium chloride	BP	Calcium chloride dihydrate		ü	ü			ü
28	52538	Calcium gluconate	BP	calcium gluconate monohydrate	BP*	ü	ü	ü		ü
29	52542	Calcium hydrogen phosphate	BP	calcium hydrogen phosphate dihydrate	BP*	ü	ü	ü	ü	ü
30	95202	Calcium hydrogen phosphate anhydrous	BP	calcium hydrogen phosphate	BP*	ü	ü	ü	ü	ü
31	100565	Calcium lactate anhydrous	BP	calcium lactate	BP*		ü	ü		ü
32	63405	Calcium sulfate	BPAP	calcium sulfate hemihydrate	BPAP*	ü	ü	ü	ü	ü
33	92089	Calcium sulfate anhydrous	USP	calcium sulfate		ü		ü		ü
36	91543	Caldiamide sodium	BAN	caldiamide sodium hydrate	BAN*	ü				ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Prescription	Export Only	Listed	Registered comp. Over the counter	Meets INN Policy?
37	60531	Caprylic/capric triglyceride	ICID	medium chain triglycerides	BP	ü	ü	ü	ü	ü
38	52685	Cellacephate	BP	cellacefate		ü	ü	ü	ü	ü
39	89270	Cetareth-12	ICID	cetearomacrogol 600	ICID*			ü	ü	ü
40	90085	Cetareth-17	ICID	cetearomacrogol 850	ICID*				ü	ü
41	73387	Cetareth-20	ICID	cetearomacrogol 1000	ICID*	ü	ü	ü	ü	ü
42	90079	Cetareth-25	ICID	Cetearomacrogol 1250	ICID*			ü	ü	ü
43	85415	Cetareth-30	ICID	Cetearomacrogol 1500	ICID*			ü		ü
44	81271	Cetareth-6	ICID	cetearomacrogol 300	ICID*				ü	ü
45	94232	Ceteth-2	ICID	cetomacrogol 100	INN*			ü	ü	ü
46	94236	Ceteth-24	ICID	cetomacrogol 1200	INN*			ü		ü
47	89428	Cetyl dimethicone	ICID	cetyl dimeticone	ICID*		ü	ü		ü
48	92177	Cetyl dimethicone copolyol	ICID	cetyl macrogol/PPG-500/1 dimeticone	ICID*		ü	ü		ü
49	52739	Chlorbutol	BP	chlorobutanol hemihydrate	BP*	ü	ü		ü	ü
50	52779	Chlorpheniramine maleate	BP	chlorphenamine maleate					ü	ü
51	52796	Cholecalciferol	BP	colecalfiferol			ü	ü	ü	ü
52	73378	Choleth-24	ICID	cholomacrogol 1200	ICID*			ü		ü
53	95567	cis-3-Hexenyl caproate	PFC	cis-3-hexenyl hexanoate	PFC*		ü	ü		ü
54	97419	Citric acid - anhydrous	BP	citric acid	BP*	ü	ü	ü	ü	ü
55	73497	Coco-caprylate/caprates	ICID	coco-octanoate/decanoate	ICID*				ü	ü
56	91242	Corn oil PEG-6 esters	ICID	macrogol 300 corn oil esters	ICID*	ü				ü
57	94806	Cupric sulfate anhydrous	MI	copper (II) sulfate	MI*			ü		
58	94810	Cupric sulfate pentahydrate	MI	copper (II) sulfate pentahydrate	USP*	ü				
59	53048	Cyclomethicone	USP	cyclometicone	USP*	ü	ü	ü	ü	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Prescription	Export Only	Listed	Registered comp.	Over the counter	Meets INN Policy?
60	105603	DEA-C8-18 perfluoroalkylethyl phosphate	ICID	diolamine C8-18 perfluoroalkylethyl phosphate	ICID*					ü	ü
61	70697	DEA-cetyl phosphate	ICID	diolamine cetyl phosphate	ICID*		ü	ü		ü	ü
62	100780	DEA-Oleth-3 phosphate	ICID	diolamine olomacrogol 150 phosphate	ICID*			ü		ü	ü
63	63559	Decan-1-ol	BPAP	decyl alcohol		ü	ü	ü		ü	ü
64	68290	Diazolidinylurea	ICID	diazolidinyl urea		ü	ü	ü	ü	ü	ü
65	96353	Diethyl toluamide	ICID	diethyltoluamide	INN		ü	ü			ü
66	53250	Di-isopropanolamine	USP	diisopropanolamine			ü			ü	ü
67	85525	Dimethicone 10	BP	dimeticone 10	BP*			ü			ü
68	91502	Dimethicone 100	BP	dimeticone 100	BP*	ü	ü	ü		ü	ü
69	58347	Dimethicone 1000	BP	dimeticone 1000	BP*	ü		ü		ü	ü
70	96967	Dimethicone 1510	BP	dimeticone 1510	BP*	ü	ü			ü	ü
71	96336	Dimethicone 20	BP	dimeticone 20	BP*			ü		ü	ü
72	73472	Dimethicone 200	BP	dimeticone 200	BP*	ü	ü	ü		ü	ü
73	104415	Dimethicone 30	BP	dimeticone 30	BP*			ü			ü
74	64435	Dimethicone 350	BP	dimeticone 350	BP*	ü	ü	ü		ü	ü
75	84714	Dimethicone 450	BP	dimeticone 450	BP*	ü		ü			ü
76	98931	Dimethicone 5	BP	dimeticone 5	BP*		ü	ü			ü
77	80938	Dimethicone 50	BP	dimeticone 50	BP*			ü			ü
78	66689	Dimethicone copolyol	ICID	dimeticone copolyol	ICID*		ü	ü		ü	ü
79	94065	Dimethicone copolyol phosphate	ICID	dimeticone copolyol phosphate	ICID*			ü			ü
80	66554	Dimethiconol	ICID	dimeticonol	ICID*	ü		ü		ü	ü
81	101709	Dimethiconol stearate	ICID	dimeticonol stearate	ICID*			ü			ü
82	95372	Di-N propyl isocinchomeronate	CAS	di-n-propyl isocinchomeronate			ü	ü			ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Prescription	Export Only	Listed	Registered comp. Over the counter	Meets INN Policy?
83	53315	Diphenyl ether	MI	diphenyl oxide			ü		ü	ü
84	102486	Disodium dimethicone copolyol sulfosuccinate	ICID	disodium dimeticone copolyol sulfosuccinate	ICID*				ü	ü
85	74330	Disodium laurethsulfosuccinate	ICID	disodium lauromacrogolsulfosuccinate	ICID*		ü		ü	ü
86	103021	Disodium oleamido PEG-2 sulfosuccinate	ICID	disodium oleamido macrogol 100 sulfosuccinate	ICID*		ü			ü
87	91701	Disteareth-6 dimonium chloride	ICID	distearomacrogol 300 dimonium chloride	ICIL*			ü		ü
88	102195	dl-alpha tocopherol phosphate disodium	CAS	dl-alpha-tocopheryl phosphate disodium		ü				
89	93271	dl-alpha tocopheryl acetate	BP	dl-alpha-tocopheryl acetate	USP*	ü	ü	ü	ü	
90	59836	DMDM Hydantoin	ICID	dimethylol dimethyl hydantoin	ICID*		ü	ü		ü
91	87433	Edetate dipotassium	MI	edetate dipotassium dihydrate	USAN*				ü	ü
92	91756	Eosine	MAR	acid red 87			ü			
93	53463	Ethanolamine	BP	monoethanolamine	INN	ü	ü	ü	ü	ü
94	81464	Ether - solvent	BP	ether					ü	ü
95	100719	Ethyl oenanthate	MI	ethyl enantate	INN*				ü	ü
96	53547	Ethyl oenanthate	MI	ethyl enantate	INN*	ü	ü	ü	ü	ü
97	53515	Ethylene glycol monostearate	MAR	ethylene glycol monopalmitostearate	BP			ü	ü	ü
98	93574	Ethylene/VA copolymer	ICID	ethylene/vinyl acetate copolymer	ICID*	ü	ü	ü	ü	ü
99	94793	Ferric ammonium citrate	MAR	iron (III) ammonium citrate	USP*	ü				
100	94818	Ferric chloride anhydrous	MAR	iron(III) chloride	MI*	ü				
101	58044	Ferric manganese peptonate	TGA	iron (III) manganese (II) peptonate					ü	
102	92469	Ferric nitrate	BPAP	iron (III) nitrate nonahydrate	BPAP*	ü				
103	53622	Ferric oxide	MI	iron (III) oxide	USP*	ü	ü	ü	ü	

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Prescription	Export Only	Listed	Registered comp.	Over the counter	Meets INN Policy?
104	53624	Ferric pyrophosphate	MI	iron (III) pyrophosphate	MI*			ü			
105	53627	Ferrosoferric oxide	MI	iron oxide	MI*	ü				ü	
106	53631	Ferrous fumarate	BP	iron (II) fumarate	BP*		ü	ü			
107	69280	Ferrous sulfate	BP	iron (II) sulfate heptahydrate	BP*	ü					
108	68856	Ferrous sulfate - dried	BP	iron (II) sulfate	BP*			ü			
109	53790	Glucose	BP	glucose monohydrate	BP*	ü	ü	ü	ü	ü	ü
110	58055	Glucose - anhydrous	BP	glucose	BP*	ü	ü	ü		ü	ü
111	53795	Glutaraldehyde	BP	glutaral	INN	ü					ü
112	94891	Glycerol triacetate	BPAP	triacetin		ü	ü	ü	ü	ü	ü
113	53805	Glyceryl mono-oleate	MAR	glyceryl monooleate	USP	ü	ü	ü		ü	ü
114	61974	Glycol stearate	ICID	ethylene glycol monopalmitostearate				ü		ü	ü
115	73454	Glycollic acid	MI	glycolic acid			ü	ü			ü
116	85484	Glycyrrhetic acid	ICID	enoxolone	BP			ü			ü
117	72588	Hercolyn	PFC	methyl hydrogenated rosinat			ü	ü		ü	ü
118	53994	Hydroxyethylcellulose	BP	hyetellose	INN	ü	ü	ü		ü	ü
119	53995	Hydroxyethylmethylcellulose	BP	hymetellose	INN		ü	ü		ü	ü
120	98413	Hydroxypropyl beta cyclodextrin	USP	hydroxypropylbetadex	BP	ü		ü			ü
121	67610	Hydroxypropylcellulose	BP	hypolose	INN	ü	ü	ü	ü	ü	ü
122	81590	Hydroxyquinoline sulfate	MAR	oxyquinoline sulfate	USP					ü	ü
123	54067	Insulin - human	BP	insulin		ü					ü
124	54148	Isoascorbic acid	MI	erythorbic acid	USP		ü				ü
125	92254	Isoceteth-20	ICID	isocetomacrogol 1000	ICID*					ü	ü
126	89431	iso-Cyclocitral	PFC	isocyclocitral				ü		ü	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Prescription	Export Only	Listed	Registered comp.	Over the counter	Meets INN Policy?
127	54200	Isopropyl adipate	PFC	diisopropyl adipate	MAR			ü		ü	ü
128	95457	Isopropyl hydroxybenzoate	ICID	isopropyl 4-hydroxybenzoate				ü		ü	ü
129	105760	Isopropyl PPG-2 isodeceth-7 carboxylate	ICID	isopropyl PPG-2 isodecomacrogol 350 carboxylate	ICID*			ü			ü
130	54252	Lactose	BP	lactose monohydrate	BP*	ü	ü	ü	ü	ü	ü
131	79271	Lactose anhydrous	BP	lactose	BP*	ü	ü	ü	ü	ü	ü
132	94389	Laneth-5	ICID	lanomacrogol 250	ICID*	ü					ü
133	94204	Laureth-10	ICID	lauromacrogol 500	INN*		ü			ü	ü
134	94230	Laureth-12	ICID	lauromacrogol 600	INN*					ü	ü
135	104074	Laureth-2	ICID	lauromacrogol 100	INN*					ü	ü
136	94231	Laureth-23	ICID	lauromacrogol 1150	INN*		ü	ü		ü	ü
137	94225	Laureth-3	ICID	lauromacrogol 150	INN*			ü		ü	ü
138	94226	Laureth-4	ICID	lauromacrogol 200	INN*		ü	ü		ü	ü
139	94227	Laureth-7	ICID	lauromacrogol 350	INN*			ü			ü
140	94228	Laureth-8	ICID	lauromacrogol 400	INN*	ü	ü	ü			ü
141	94229	Laureth-9	ICID	lauromacrogol 450	INN*			ü		ü	ü
142	61067	Lauryl diethanolamide	CAS	lauramide DEA						ü	ü
143	105115	Lauryl PEG/PPG-18/18 Methicone	ICID	lauryl macrogol/PPG-900/18 meticone	ICID*			ü			ü
144	105945	Lauryl PEG-9 polydimethylsiloxethyl dimeticone	ICID	lauryl macrogol 450 polydimethylsiloxethyl dimeticone	ICID*			ü			ü
145	89539	Laurylmethicone copolyol	ICID	laurylmeticone copolyol	ICID*			ü			ü
146	94548	Lime	USP	calcium oxide				ü			ü
147	106236	Macrogol 6 glycerol caprylocaprate	EP	macrogol 300 glycerol caprylocaprate	EP*					ü	ü
148	54386	Magnesium aspartate	MAR	magnesium aspartate tetrahydrate	MAR*			ü			ü

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149	54388	Magnesium carbonate	USP	magnesium carbonate hydrate	USP*	ü	ü	ü	ü	ü
150	57943	Magnesium carbonate - heavy	BP	heavy magnesium carbonate		ü		ü	ü	ü
151	58330	Magnesium carbonate - light	BP	light magnesium carbonate		ü	ü	ü	ü	ü
152	54389	Magnesium chloride	BP	magnesium chloride hexahydrate		ü	ü	ü	ü	ü
153	54398	Magnesium phosphate	USP	magnesium phosphate pentahydrate	USP*			ü		ü
154	68917	Magnesium sulfate	BP	magnesium sulfate heptahydrate		ü	ü	ü	ü	ü
155	61598	Manganese gluconate	USP	manganese (II) gluconate	USP*			ü		
156	68918	Manganese sulfate	BP	manganese (II) sulphate tetrahydrate	BP*	ü				
157	94872	Manganese sulfate monohydrate	BP	manganese (II) sulfate monohydrate	BP*		ü			
158	72290	Meglumine pentetate	BP	pentetate meglumine	TGA	ü				ü
159	54475	Menthol	USP	racementhol	INN	ü	ü	ü	ü	ü
160	54478	Menthyl acetate	MI	l-menthyl acetate	BP*	ü	ü	ü	ü	ü
161	81335	meta-Cresol	MI	metacresol	USAN	ü				ü
162	61429	Methyl sulfide	MI	dimethyl sulfide		ü		ü	ü	ü
163	77552	Monosodium glutamate	USP	monosodium glutamate monohydrate	USP*	ü	ü	ü	ü	ü
164	105508	N-(Methoxy-PEG-5000 carbamoyl)-dipalmitoylphosphatidyl ethanolamine sodium	TGA	n-(methoxy-macrogol 5000 carbamoyl)-dipalmitoylphosphatidylethanolamine sodium		ü				ü
165	96621	Neopentyl glycol dicaprylate/dicaprate	ICID	neopentyl glycol dioctanoate/didecanoate	ICID*			ü	ü	ü
166	96954	Noneth-5	ICID	nonomacrogol 250	ICID*				ü	ü
167	54971	Octyl salicylate	ICID	octisalate	INN	ü				ü
168	94220	Oleth-10	ICID	olomacrogol 500	ICID*			ü	ü	ü
169	94206	Oleth-3	ICID	olomacrogol 150	ICID*			ü	ü	ü

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170	104297	Oleth-3 phosphate	ICID	olomacrogol 150 phosphate	ICID*			ü			ü
171	94207	Oleth-5	ICID	olomacrogol 250	ICID*			ü		ü	ü
172	94222	Oleth-8	ICID	olomacrogol 400	ICID*					ü	ü
173	57963	Paraffin - soft white	BP	white soft paraffin		ü	ü	ü	ü	ü	ü
174	73811	Paraffin - soft yellow	BP	yellow soft paraffin			ü	ü		ü	ü
175	104206	PEG/PPG-18/18 dimethicone	ICID	macrogol/PPG-900/18 dimeticone	ICID*			ü			ü
176	89479	PEG-10 soya sterol	ICID	macrogol 500 soya sterol	ICID*			ü			ü
177	94276	PEG-10 stearate	ICID	macrogol 500 stearate	INN*	ü	ü			ü	ü
178	94208	PEG-100 stearate	ICID	macrogol 5000 stearate	INN*	ü	ü	ü		ü	ü
179	93604	PEG-12 dilaurate	ICID	macrogol 600 dilaurate	ICID*			ü		ü	ü
180	80255	PEG-120 methyl glucose dioleate	ICID	macrogol 6000 methyl glucose dioleate	ICID*		ü	ü		ü	ü
181	73763	PEG-15 cocamine	ICID	macrogol 750 cocamine	ICID*		ü	ü		ü	ü
182	75948	PEG-150 distearate	ICID	macrogol 7500 distearate	ICID*	ü	ü			ü	ü
183	104201	PEG-20 Almond glycerides	ICID	macrogol 1000 almond glycerides	ICID*			ü			ü
184	96728	PEG-20 glyceryl oleate	ICID	Macrogol 1000 glyceryl oleate	ICID*					ü	ü
185	102737	PEG-20 Glyceryl stearate	ICID	macrogol 1000 glyceryl stearate	ICID*					ü	ü
186	94067	PEG-20 methyl glucose sesquistearate	ICID	macrogol 1000 methyl glucose sesquistearate	ICID*	ü		ü			ü
187	94277	PEG-20 stearate	ICID	macrogol 1000 stearate	INN*	ü	ü	ü		ü	ü
188	93514	PEG-3 distearate	ICID	macrogol 150 distearate	ICID*	ü	ü			ü	ü
189	97961	PEG-30 dipolyhydroxystearate	ICID	macrogol 1500 dipolyhydroxystearate	ICID*		ü	ü		ü	ü
190	94278	PEG-30 stearate	ICID	macrogol 1500 stearate	INN*					ü	ü
191	107517	PEG-32 stearate	ICID	macrogol 1600 stearate	INN*					ü	ü
192	96046	PEG-35 castor oil	ICID	macrogol 1750 castor oil	ICID*	ü	ü	ü		ü	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Prescription	Export Only	Listed	Registered comp. Over the counter	Meets INN Policy?
193	91233	PEG-4 dilaurate	ICID	macrogol 200 dilaurate	ICID*			ü	ü	ü
194	98740	PEG-4 Laurate	ICID	macrogol 200 laurate	INN*		ü	ü		ü
195	94282	PEG-4 stearate	ICID	macrogol 200 stearate	INN*	ü	ü	ü	ü	ü
196	96047	PEG-40 castor oil	ICID	macrogol 2000 castor oil	ICID*			ü		ü
197	96048	PEG-40 hydrogenated castor oil	ICID	macrogol 2000 hydrogenated castor oil	ICID*	ü	ü	ü	ü	ü
198	60534	PEG-40 sorbitan peroleate	ICID	macrogol 2000 sorbitan peroleate	ICID*				ü	ü
199	94280	PEG-40 stearate	ICID	macrogol 2000 stearate	INN*	ü	ü	ü	ü	ü
200	88351	PEG-5 glyceryl stearate	ICID	macrogol 250 glyceryl stearate	ICID*			ü		ü
201	94831	PEG-50 stearate	ICID	macrogol 2500 stearate	INN*				ü	ü
202	96852	PEG-55 propylene glycol oleate	ICID	macrogol 2750 propylene glycol oleate	ICID*			ü		ü
203	92936	PEG-6 lauramide	ICID	macrogol 300 lauramide	ICID*				ü	ü
204	107516	PEG-6 stearate	ICID	macrogol 300 stearate	INN*				ü	ü
205	98176	PEG-60 Almond Glycerides	ICID	macrogol 3000 almond glycerides	ICID*			ü	ü	ü
206	95034	PEG-60 glyceryl isostearate	ICID	macrogol 3000 glyceryl isostearate	ICID*			ü		ü
207	96370	PEG-60 hydrogenated castor oil	ICID	macrogol 3000 hydrogenated castor oil	ICID*	ü			ü	ü
208	96935	PEG-7 cocamide	ICID	macrogol 350 cocamide	ICID*				ü	ü
209	99310	PEG-7 glyceryl cocoate	ICID	macrogol 350 glyceryl cocoate	ICID*		ü	ü	ü	ü
210	96052	PEG-7 hydrogenated castor oil	ICID	macrogol 350 hydrogenated castor oil	ICID*			ü		ü
211	94258	PEG-7 stearate	ICID	macrogol 350 stearate	INN*				ü	ü
212	75949	PEG-75 lanolin	ICID	macrogol 3750 lanolin	ICID*			ü	ü	ü
213	104175	PEG-75 Stearate	ICID	macrogol 3750 stearate	INN*			ü		ü
214	104571	PEG-8 behenate	ICID	macrogol 400 behenate	INN*	ü				ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Prescription	Export Only	Listed	Registered comp.	Over the counter	Meets INN Policy?
215	105426	PEG-8 cetyl dimethicone	ICID	macrogol 400 cetyl dimeticone	ICID*			ü			ü
216	98359	PEG-8 dilaurate	ICID	macrogol 400 dilaurate	ICID*					ü	ü
217	91399	PEG-8 distearate	ICID	macrogol 400 distearate	ICID*			ü			ü
218	105870	PEG-8 laurate	ICID	macrogol 400 laurate	INN*						ü
219	92168	PEG-8 ricinoleate	ICID	macrogol 400 ricinoleate	ICID*	ü					ü
220	60499	PEG-8 stearate	ICID	macrogol 400 stearate	INN*	ü		ü		ü	ü
221	92755	Pentaerythrityl tetraoctanoate	ICID	pentaerythrityl tetralaurate				ü			ü
222	71558	Phenyl trimethicone	ICID	phenyl trimeticone				ü		ü	ü
223	90922	Phenylbenzimidazole sulfonic acid	ICID	ensulizole	INN			ü			ü
224	56532	Phytic acid	MI	lytic acid	INN	ü					ü
225	98644	Polyethylene glycol monomethyl ether	USP	macrogol monomethyl ether	USP*	ü	ü				ü
226	91937	Polystyrene sulfonate	USP	polystyrene sulfonate - hydrogen	USP*	ü					ü
227	55421	Potassium acid tartrate	MAR	potassium hydrogen tartrate	BP	ü				ü	ü
228	104549	PPG-1-PEG 9 lauryl glycol ether	ICID	PPG-1-macrogol 450 lauryl glycol ether	ICID*				ü		ü
229	97054	PPG-5-ceteth-20	ICID	PPG-5-cetomacrogol 1000	ICID*			ü			ü
230	104581	Propylene glycol dicaprinate	ICID	propylene glycol didecanoate	ICID*			ü			ü
231	93569	Propylene glycol dicaprylate/dicaprate	ICID	propylene glycol dioctanoate/didecanoate	ICID*		ü	ü			ü
232	91753	Propylene glycol isoceteth-3 acetate	ICID	propylene glycol isocetomacrogol 150 acetate	ICID*			ü			ü
233	92183	PVP/VA Copolymer	ICID	copovidone		ü	ü	ü		ü	ü
234	102239	R,S-alpha Lipoic acid	CAS	alpha lipoic acid	USP	ü		ü			ü
235	68280	Retinyl acetate	BP	retinol acetate	INN*	ü	ü	ü	ü		ü
236	63235	Retinyl palmitate	BP	retinol palmitate	INN*	ü	ü	ü		ü	ü

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237	55685	Rutin	MI	rutoside	INN		ü	ü			ü
238	55783	Sodium calciumedetate	BP	sodium calcium edetate		ü	ü			ü	ü
239	55785	Sodium carbonate anhydrous	BP	sodium carbonate	BP*	ü	ü	ü		ü	ü
240	90041	Sodium citrate anhydrous	BP	sodium citrate		ü	ü			ü	ü
241	88320	Sodium laureth sulfate	ICID	sodium lauromacrogol sulfate	ICID*	ü	ü	ü		ü	ü
242	96762	Sodium lauryl di(oxyethyl) sulfate	CAS	sodium lauryl di(oxyethyl) sulfate			ü				ü
243	68471	Sodium lauryl sulfate	BP	sodium lauryl sulfate	BP*	ü	ü	ü	ü	ü	ü
244	75660	Sodium lauryl sulfoacetate	ICID	sodium lauryl sulfoacetate						ü	ü
245	97536	Sodium methoxy PEG-40-carbonyl-distearoylphosphatidylethanolamine	TGA	sodium methoxy macrogol 2000 carbonyl-distearoylphosphatidylethanolamine	TGA	ü					ü
246	90080	Sodium phosphate - dibasic anhydrous	USP	sodium phosphate - dibasic		ü	ü	ü		ü	
247	103327	Sodium phosphate - monobasic anhydrous	USP	sodium phosphate - monobasic	USP*	ü					
248	55889	Sodium stearyl 2-lactylate	ICID	sodium stearyl lactylate				ü		ü	ü
249	69098	Sodium sulfate	BP	sodium sulfate decahydrate	BP*		ü	ü			ü
250	93372	Sodium sulfate anhydrous	BP	sodium sulfate	BP*	ü	ü	ü		ü	ü
251	93373	Sodium sulfite anhydrous	BP	sodium sulfite	BP*	ü	ü	ü		ü	ü
252	82070	Sodium thiosulfate	BP	sodium thiosulfate pentahydrate	BP*	ü	ü			ü	ü
253	76323	Sodium trideceth sulfate	ICID	sodium tridecomacrogol sulfate	ICID*					ü	ü
254	93417	Steareth-10	ICID	stearomacrogol 500	ICID*	ü					ü
255	97791	Steareth-100	ICID	stearomacrogol 5000	ICID*			ü			ü
256	93416	Steareth-2	ICID	stearomacrogol 100	ICID*	ü	ü	ü		ü	ü

#	ID	Current Name	Current Ref	Proposed Name	New Ref	Prescription	Export Only	Listed	Registered comp. Over the counter	Meets INN Policy?
257	92964	Steareth-20	ICID	stearomacogol 1000	ICID*			ü		ü
258	94405	Steareth-21	ICID	stearomacrogol 1050	ICID*	ü		ü	ü	ü
259	74339	TEA-lauryl sulfate	ICID	trolamine lauryl sulfate	ICID*				ü	ü
260	89498	Triceteareth-4 phosphate	ICID	tricetearomacrogol 200 phosphate	ICID*				ü	ü
261	56275	Triethanolamine	BP	trolamine	INN	ü	ü	ü	ü	ü
262	74920	Triethanolamine lauryl sulfate	ICID	trolamine lauryl sulfate	ICID*		ü	ü	ü	ü

Appendix 10: Names proposed for dual labelling

Table 12: Ingredient names proposed for dual labelling

#	Id	Ingredient name	Ref	Proposed new ingredient name	New Ref
1	58903	Actinomycin D	BAN	Dactinomycin	
2	51982	Adrenaline	BP	Epinephrine	INN
3	51983	Adrenaline acid tartrate	BP	Epinephrine acid tartrate	BP
4	51985	Adrenaline hydrochloride	BP	Epinephrine hydrochloride	BP
5	52086	Amethocaine hydrochloride	BP	Tetracaine hydrochloride	USAN
6	52137	Amphotericin	BP	Amphotericin B	
7	52166	Amylobarbitone sodium	BP	Amobarbital sodium	
8	96610	Bacillus Calmette and Guérin	BP	Mycobacterium bovis (BCG strain)	
9	52304	Benzhexol hydrochloride	BP	Trihexyphenidyl hydrochloride	
10	52966	Colaspase	BAN	Asparaginase	USAN
11	93010	Co-methylcobalamin	MI	Mecobalamin	INN
12	94811	Crystal violet C142555	MAR	Methylrosanilinium Chloride	INN
13	97278	Cysteamine bitartrate	BAN	Mercaptamine bitartrate	
14	53367	Dotiepin hydrochloride	BP	Dosulepin hydrochloride	
15	53373	Doxycycline hydrochloride	BP	Doxycycline hyclate	
16	96965	Eformoterol	BAN	Formoterol	
17	97220	Eformoterol fumarate	BAN	Formoterol fumarate	BP
18	97221	Eformoterol fumarate dihydrate	BAN	Formoterol fumarate dihydrate	BP
19	53730	Frusemide	BP	Furosemide	
20	102321	Frusemide sodium	BP	Furosemide sodium	
21	53814	Glycopyrrolate	USP	Glycopyrronium bromide	INN
22	54017	Hydroxyurea	BP	Hydroxycarbamide	

#	Id	Ingredient name	Ref	Proposed new ingredient name	New Ref
23	54311	Lignocaine hydrochloride	BP	Lidocaine hydrochloride monohydrate	
24	93311	Lignocaine hydrochloride anhydrous	BP	Lidocaine hydrochloride	BAN
25	54907	Noradrenaline acid tartrate	BP	Norepinephrine acid tartrate monohydrate	
26	93223	Noradrenaline	BAN	Norepinephrine	INN
27	55037	Oxpentifylline	BP	Pentoxifylline	INN
28	55214	Phenobarbitone	BP	Phenobarbital	INN
29	55215	Phenobarbitone sodium	BP	Phenobarbital sodium	INN
30	81933	Piperazine oestrone sulfate	MAR	Estropipate	BP
31	55500	Procaine penicillin	BP	Procaine benzylpenicillin	
32	55696	Salcatonin	BP	Calcitonin (salmon)	INN
33	56101	Tetracosactrin	BP	Tetracosactide	INN
34	56288	Trimeprazine tartrate	BP	Alimemazine tartrate	

Historical consultation document

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R12/685715