

Consultation submission cover sheet

This form accompanies a submission on:

International Harmonisation of Ingredient Names	
Name and designation	<div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 120px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 80px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 120px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 50px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 250px; height: 15px;"></div>
Company/organisation name and address	Multiple areas represented
Contact phone number	<div style="background-color: black; width: 250px; height: 15px;"></div>
I would like the comments I have provided to be kept confidential and not be published: <i>(Please give reasons and identify specific sections of response if applicable)</i>	
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
I do not object to publication of my submission, but would like my name to be removed from all documents prior to publication and for my name to not be included within the list of submissions on the TGA website.	
	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, a: <i>(tick all that apply)</i>	
Business in the therapeutics industry <i>(please tick sector)</i> :	
<input type="checkbox"/> Prescription medicines	<input type="checkbox"/> Complementary medicines <input type="checkbox"/> OTC medicines
<input type="checkbox"/> Medical devices	<input type="checkbox"/> Blood, tissues, biological <input type="checkbox"/> Other
<input type="checkbox"/> Sole trader	<input type="checkbox"/> Business with employees
<input type="checkbox"/> Importer	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Supplier <input checked="" type="checkbox"/> Industry organisation
<input checked="" type="checkbox"/> Government	<input type="checkbox"/> Researcher <input type="checkbox"/> Professional body
<input type="checkbox"/> Consumer organisation	<input type="checkbox"/> Institution (e.g. university, hospital)

I am, or I represent, a: *(tick all that apply)*

- Regulatory affairs consultant Laboratory professional
- Health professional – *please indicate type of practice:* Pharmacist
- Other - *please specify:* Medicines terminology development

If you would like to be kept informed about TGA activities, please subscribe to one of the TGA's email lists <<http://www.tga.gov.au/newsroom/subscribe.htm>>.

It would help in the analysis of stakeholder comments if you provide the information requested below.

Responses to General Questions in the IHIN consultation paper	
Question	Response
<i>General questions on the proposed name changes (page13)</i>	
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?	Please refer to attached document for all responses
<i>General questions on the proposal for dual labelling (page 16)</i>	
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?	
<i>General questions on the potential impact of the proposed name changes for Implications for Consumers and healthcare professionals (page 16)</i>	
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?	
<i>General questions on the potential impact of the proposed name changes for sponsors (page 17)</i>	
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?	

Responses to General Questions in the IHIN consultation paper

General question on proposed transitional period (page 19)

<p>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?</p>	
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Additional comments or areas requiring clarification in the IHIN consultation paper

Section, page number	Comments

Responses to General Questions on the update to TGA Approved terminology for medicines (page 20)

Question	Answer
<p>9. Do you believe anything is missing from this document? If so, please specify.</p>	
<p>10. Do you agree that the updated document is more user-friendly?</p>	
<p>11. Will this update to the guidance assist you in proposing new ingredient names?</p>	

Responses to General Questions on the update to TGA Approved terminology for medicines (page 20)

<p>12. Are there any general concerns with the updates to the structure of <i>TGA Approved terminology for medicines</i>?</p>	
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Suggested improvements, amendments, corrections and areas requiring clarification in the draft *TGA Approved Terminology for medicines* guidance document

Section, page number	Comments

Comments and areas requiring clarification in the list of ingredient names (appendices 1 to 10 of IHIN consultation paper)

Name and ID of Ingredient	Comments

Any other additional comments

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Document Review Form

Document ID, Version & Name	Notes
International Harmonisation of Ingredient Names (IHIN) Consultation paper Version 1.0, May 2013	

Review Information

Reviewer's Name and Designation	[REDACTED]		
Review start	1 July 2013	Review finish	9 July 2013

Section Heading or question	Reviewer Comment																						
Introduction																							
The importance of harmonisation	There is no mention of the scheduled end date.																						
Summary of proposed name changes																							
Derivatives of a substance	It is not clear if there is any plan to add all parents of derivatives? e.g. cefalotin sodium exists but cefalotin does not																						
Proposed changes to ingredient names																							
Question 1	<p data-bbox="786 576 1447 603"><u>Search issues in electronic management systems</u></p> <p data-bbox="786 624 1529 651">Concern around potential difficulty searching for terms:</p> <ul data-bbox="835 671 2056 831" style="list-style-type: none"> • where they begin with unusual detail (e.g. 'dl' as in (#14) dl-alpha-tocopherol; L at the beginning of(#315) L-menthyl acetate) • where the name/spelling change occurs in the first few letters of the name (e.g. (#92) cholecalciferol/colecalciferol; (#117) cyclosporine/ciclosporin; (#93) cholestyramine/colestyramine) <p data-bbox="786 900 1189 927"><u>Order of components in terms</u></p> <table border="1" data-bbox="786 943 2033 1417"> <thead> <tr> <th data-bbox="786 943 999 994">#</th> <th data-bbox="999 943 1518 994">documented term</th> <th data-bbox="1518 943 2033 994">suggested term</th> </tr> </thead> <tbody> <tr> <td data-bbox="786 994 999 1045">18</td> <td data-bbox="999 994 1518 1045">hydrated aluminium hydroxide</td> <td data-bbox="1518 994 2033 1045">aluminium hydroxide hydrated</td> </tr> <tr> <td data-bbox="786 1045 999 1193">28</td> <td data-bbox="999 1045 1518 1193">strong ammonia solution/dilute ammonia solution</td> <td data-bbox="1518 1045 2033 1193">separate terms: ammonia solution strong ammonia solution dilute</td> </tr> <tr> <td data-bbox="786 1193 999 1275">158</td> <td data-bbox="999 1193 1518 1275">disodium lauromacrogolsulfosuccinate</td> <td data-bbox="1518 1193 2033 1275">lauromacrogolsulfosuccinate disodium</td> </tr> <tr> <td data-bbox="786 1275 999 1326">294</td> <td data-bbox="999 1275 1518 1326">heavy magnesium carbonate</td> <td data-bbox="1518 1275 2033 1326">magnesium carbonate heavy</td> </tr> <tr> <td data-bbox="786 1326 999 1377">295</td> <td data-bbox="999 1326 1518 1377">light magnesium carbonate</td> <td data-bbox="1518 1326 2033 1377">magnesium carbonate light</td> </tr> <tr> <td data-bbox="786 1377 999 1422">354</td> <td data-bbox="999 1377 1518 1422">white soft paraffin</td> <td data-bbox="1518 1377 2033 1422">paraffin white soft</td> </tr> </tbody> </table>		#	documented term	suggested term	18	hydrated aluminium hydroxide	aluminium hydroxide hydrated	28	strong ammonia solution/dilute ammonia solution	separate terms: ammonia solution strong ammonia solution dilute	158	disodium lauromacrogolsulfosuccinate	lauromacrogolsulfosuccinate disodium	294	heavy magnesium carbonate	magnesium carbonate heavy	295	light magnesium carbonate	magnesium carbonate light	354	white soft paraffin	paraffin white soft
#	documented term	suggested term																					
18	hydrated aluminium hydroxide	aluminium hydroxide hydrated																					
28	strong ammonia solution/dilute ammonia solution	separate terms: ammonia solution strong ammonia solution dilute																					
158	disodium lauromacrogolsulfosuccinate	lauromacrogolsulfosuccinate disodium																					
294	heavy magnesium carbonate	magnesium carbonate heavy																					
295	light magnesium carbonate	magnesium carbonate light																					
354	white soft paraffin	paraffin white soft																					

355	yellow soft paraffin	paraffin yellow soft
329	green lipped mussel	mussel green lipped
344	conjugated estrogens	estrogens conjugated
438	sodium calcium edetate	edetate sodium calcium
440	sodium citrate	citrate sodium
441	sodium amidotrizoate	amidotrizoate sodium
447	sodium phosphate – dibasic	phosphate sodium dibasic
448	sodium phosphate – monobasic	phosphate sodium monobasic
451	sodium sulfate	sulfate sodium
452	sodium sulfite	sulfite sodium
453	sodium thiosulfate pentahydrate	thiosulfate sodium pentahydrate

There is also a question around the order of the components for the various insulin ingredients, especially given that “human” is being removed from the ingredient name (#252). How will the bovine and porcine insulins be described? “insulin bovine” or “bovine insulin”

The addition of hydration status

There may be some uncertainty around the hydration status of an ingredient. Lack of hydration status in a term implies that the ingredient is anhydrous. This may differ from how ingredients are represented in an official monograph. For example doxycycline hyclate is the name of the monograph in Martindale and of the INN, yet the ingredient is actually a hemi-hydrate molecule.

Dual naming

Should cholecalciferol, cholestyramine and ciclosporin be added to the list of dual names, given the potential of issues with searching in electronic systems. (comparing this to including frusemide/furosemide). It is not clear from this document why certain ingredients have been chosen for dual naming. Is it a safety issue or a search issue, or something else?

Application of Rules

The "Summary of proposed name changes" (page 12) section details rules which do not appear to be followed in the creation of some of the new terms. Examples include:

"Word order for salts" – see table above

"The use of isolated numbers and letters should be avoided, as should hyphens"

- isolated letter added to (#34) Amphotericin changes to amphotericin B
- hyphen retained in
 - (#299) magnesium phosphate – tribasic
 - (#346) estrone sulfate – sodium
 - (#414) polystyrene sulfonate – hydrogen
 - (#447) sodium phosphate – dibasic
 - (#448) sodium phosphate - monobasic

Acronyms

mycobacterium bovis (BCG strain) – An interesting change given that it moves away from the acronym wording but retains the acronym, and that this is not done in accordance with and standard/policy documented here.

Acceptance of INN

Several newly created terms are not the INN. For example:

#	documented term	INN
310	iothalamate meglumine	meglumine iotalamate#*
311	iotroxate meglumine	meglumine iotroxate*
312	ioxaglate meglumine	meglumine ioxaglate*
420	pralidoxime methiodide	pralidoxime iodide

query around spelling – refer to table on page 12

* agree with order of documented term even though it is not the INN

	<p><u>Use of forward slash</u></p> <p>The meaning of "/" is not clear. For example: (#87) cetyl macrogol/PPG-500/1 dimeticone.</p> <p><u>Casing issues</u></p> <p>It is not clear if there is any rule around case specificity. The following casing issues were noted:</p> <ul style="list-style-type: none"> • (#41) mycobacterium bovis (BCG strain) – would need to be case specific • (#267) Lactobacillus kefir - would need to be case specific • (#59) Calcium chloride dihydrate - should this be calcium chloride dihydrate • (#14) dl-alpha-tocopherol - lower and upper case may have different chemical meanings (e.g. dl versus DL) • (#8) dactinomycin and Dactinomycin are both used in the document <p><u>Spacing</u></p> <p>There are three ingredients which need a space inserted between "iron" and "(III)"</p> <ul style="list-style-type: none"> • (#188) iron(III) carboxymaltose • (#189) iron(III) chloride • (#190) iron(III) chloride hexahydrate
Proposed implementation of ingredient names	
Implications	<p>Suggest that there is a requirement to maintain case specificity to avoid any confusion or change of meaning. DL versus dl, amphotericin B versus amphotericin b, etc.</p> <p>There could be a need to distinguish between the old term and the new term. How is it apparent that the ingredient name has changed? Will there be a notification process or report of recent changes.</p>
Proposed implementation of ingredient names	
Names proposed for dual labelling	<p>Suggest including the reasons for why these ingredients were identified as needing dual labelling.</p> <p>In this example, adrenaline (epinephrine), we have assumed this will be a TGA approved order. If this is the approved order then will the order be reversed part way through the period so users see the new name first, in order to change the focus to the new name.</p> <p>Or should this be reversed from the beginning, with the new name appearing first. i.e. epinephrine (adrenaline)</p>

Proposed implementation of ingredient names	
Implications for sponsors	Need to ensure the label, PI and CMI are all changed at the same time
	Changing ingredient name may cause confusion for generic products. It is suggested that generic type trade names should be changed to harmonise with the new ingredient name. However it is probably not advisable to have the bracketed part of dual names in the trade name. Perhaps only the new ingredient name should be the new trade name.
Proposed implementation of ingredient names	
Proposed transitional requirements	Suggest labels, CMI and PI and are all changed at the same time.
TGA approved terminology for medicines	
Update to ingredients	How often are the ingredient lists updated
Appendix 1	
	Need a list of approved references for the acronyms used in this table.
Overall comments	
Time period	Sufficient time should be allowed for all the changes to be made and flow through from sponsor to TGA and back to sponsor for changing label, PI and CMI. These changes then need to be made throughout the pharmaceutical industry, including all electronic systems, decision support and any other data distributors.
Education	TGA should ensure that there is adequate education for all health professionals and consumers around the name changes especially for products which require dual labelling.
Collaboration TGA/PBS	Needs to be a collaborative process to ensure name changes flow from TGA down through the process to all end users.
Dual labelling	Inclusion of dual names may cause problems with dispensing labels, due to the length of the terms. This issue is even more pronounced when two or more of the dual name ingredients appear in a product. For example: lignocaine hydrochloride (lidocaine hydrochloride) 0.5% (100 mg/20 mL) + adrenaline (epinephrine)1 in 200 000 (100 microgram/20 mL) injection, 5 x 20 mL vials

Transition of ingredient names	<p>Consideration needs to be given to how the industry handles a change to an ingredient across the various brands. If only one sponsor changes their label and ingredient and the other sponsors don't change at the same time then there is potential for one product to be labelled with the new ingredient and the rest of the products labelled with old ingredient. This could lead to confusion for generic dispensing where brands are switched regularly and could lead to consumers duplicating their medicines.</p> <p>For example: benzhexol hydrochloride will change to trihexyphenidyl hydrochloride. This change in ingredient name may not be obvious or communicated to a patient at the time of prescribing or dispensing, and as a result they may inadvertently take both products, not realising that they are actually the same thing.</p> <p>Is it viable to have a staged approach so all the brands for a particular ingredient are changed by the same date.</p>
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