SHPA response to International harmonisation of ingredient names (IHIN) – Dual labelling transition to sole medicine ingredient names, December 2022

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

1. Are health professionals familiar with the proposed sole ingredient names listed in Appendix A in the consultation paper?

Yes.

The Society of Hospital Pharmacists of Australia (SHPA) is the national, professional organisation for the 6,100+ Hospital Pharmacists, and their Hospital Pharmacist Intern and Hospital Pharmacy Technician colleagues working across Australia's health system, advocating for their pivotal role improving the safety and quality of medicines use. Our members are certainly familiar with the proposed sole ingredient names listed in Appendix A in the consultation paper.

2. Do you think consumers who are currently using affected medicines are familiar with the new ingredient names?

Unsure.

3. Do you agree that all the ingredient names in Table 1 in the consultation paper can be updated to sole names at the end of the dual labelling period?

Yes.

4. Do you think mercaptamine should continue to be dual labelled as mercaptamine (cysteamine) for a longer period?

No.

5. Do you think the following ingredient names (not currently being used in medicines included in the ARTG) should remain in the dual labelling format in the Ingredients Table for historical and clarity purposes or other reasons?

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

No.

These medications are rarely used in practice and should also be changed to sole medicine ingredient names.

6. Do you think the 3-year dual labelling period due to finish on 30 April 2023 should be extended for any other ingredient names in Table 2 in the consultation paper not already mentioned in the previous 2 questions?

No.

7. Please tell us about the impacts if the dual labelling period was extended for any ingredient names. If you are a medicine sponsor, please also tell us the estimated costs of these impacts.

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N/A.

8. If the dual labelling period was extended for some ingredients, do you think the main label text size allowances in TGO 91 and TGO 92 would also need to be extended for those ingredients?

N/A.

9. Please tell us about any challenges with searching in software systems using old ingredient names that we should consider, particularly if you are or represent software vendors or are a health professional.

SHPA members of the Electronic Medication Management (EMM) specialty practice group, note that increased use of the 'unlisted medicine' functionality when prescribing, identified through systems audits conducted over the past few years in NSW, have demonstrated that clinicians do not know or recall the sole ingredient names of medications.

SHPA members also note that these changes will place a significant burden on the workload of EMM teams as they will be required to update the order catalogues and all other associated clinical decision support tools etc., to reflect the name changes. A long lead time is therefore required to ensure EMM teams can schedule this work alongside other maintenance and optimisation work already being done.

10. If you have any further comments or information you would like to share about implications and considerations for the end of dual labelling, please tell us here.

Whilst pharmacy departments may be familiar with the name changes of medications, consideration should be given to the education required to ensure medical and nursing staff are well supported, and a focus is also placed on those returning from extended leave or on new graduates.

Part 2: Transition from dual labelling to sole ingredient names

11. Do you agree with the proposal to implement a transition period to require medicine labels to be updated with sole ingredient names within a certain timeframe?

Yes.

Clarity and certainty around expected timeframes for changes to occur is required by both consumers and health professionals. A transition period is essential to allow sponsor materials and software systems to be updated, and to ensure education is provided to healthcare professionals ahead of changes.

Do you think a transition period would help in ensuring consistent and timely changes occur across all products containing specific ingredients, and would give more clarity for health professionals and consumers than the original plan?

Yes.

12. Do you agree that PI/CMI documents of affected medicines should also be updated to reflect the sole ingredient name under a transition plan?

Yes.

13. If a transition period was implemented, what do you think the transition time frame should be?

Other.

Consume Medicines Information (CMI) leaflets should reflect the information on the product packaging. A one-year transition period is sufficient to allow for old stock to be replaced. It is also an opportunity for pharmaceutical companies to review their CMIs.

Product Information (PI) leaflets may require a three-year transition period to allow practitioners who may be on leave for a period of time e.g., maternity leave, or who have not prescribed a specific medication for a while, sufficient time to familiarise themselves with the sole ingredient name.

14. Please tell us about the impacts if a transition period was implemented. If you are a medicine sponsor, please provide estimated costs of these impacts.

N/A.

15. If a transition period was implemented, do you agree with the proposal for sponsors to request updates to labels and/or PI/CMI documents to reflect the updated sole name according to existing legislation and processes?

Yes.

16. Please tell us if you have any further comments about dual labelled medicine ingredient names.

N/A.