Guidelines on compounding of medicines review - response template

The Pharmacy Board of Australia is inviting feedback on its draft revised *Guidelines for compounding of medicines* (the draft revised guidelines). Optional questions have been provided below and you may wish to address some or all of these in your response.

Published submissions will include the names (if provided) of the individuals and/or organisations making the submission unless confidentiality is requested.

Do you want your responses to be published after public consultation?

☒ Yes, I want my responses to be published after public consultation

☐ No, I do not want my responses to be published after public consultation

Submissions for website publication should be sent in Word format or equivalent.[1]

Name: [redacted]

Organisation: Department of Health Tasmania

Contact email: [redacted]

Please note this response template contains the same questions as the online survey. Please choose only ONE method of responding to avoid duplicating your submission.

[1] We aim to publish documents in accessible formats (such as word files) to meet international website accessibility guidelines. Therefore, while you are welcome to supply a PDF file of your feedback, we ask that you also provide a text or word file. More information about this is available at https://www.ahpra.gov.au/About-Ahpra/Accessibility.aspx

	Question	Your feedback (include guideline number/section)
1	The revised compounding guidelines include additional content on medicine supply pathways to consider before deciding if it is appropriate to compound a medicine (Guideline 1 When to compound medicines). **Is the new content on medicine supply pathways clear and helpful? Why or why not?**	**The new content is much improved and establishes a clear hierarchy for the supply pathway and when compounding is appropriate.** **However, this clarity will potentially lead to increased cost to the consumer especially for some medications only available via SAS pathways. In some cases, this cost may act a as a barrier to appropriate treatment. Consideration needs to be given to how the patient can access both safe and affordable treatment options.** **There is a need to consider how this guideline aligns with the National Medicines Policy in terms of encouraging timely access to affordable medicines. Cost does need to be considered in the framework – as this is a practical barrier to treatment.** **In addition, products sourced from overseas do not always represent safer options. There are numerous examples of imported products that are less safe, for example:** - **French eye drops were imported under the SAS scheme, in response to a suitable or comparable product being unavailable in the Australian market. However, the imported product did not have appropriate English instructions for reconstitution, or safe use.** - **A lack of melatonin products in a suitable presentation for dosing children led to the importation of gummies from the US. However, this Medscape articles suggest those products are problematic, and may contain inaccurate doses as well as contaminants and other active ingredients such as CBD-based compounds (https://www.medscape.com/viewarticle/991215).** - **Vials of an antiemetic medicine were imported through the SAS in response to a significant medicine shortage and high clinical need. However, these vials were unable to be used as the glass vials shattered when staff attempted to open them.**
2	The compounding guidelines advise that a copy of the formula for their compounded medicine (listing all active ingredients and their strengths, and all inactive ingredients) must be provided to the patient when requested (Guideline 13 Supporting informed patient choice). Providing	**The language used in the guideline around ingredients versus formula is confusing, the current guidance uses the terms interchangeably, however they are different things. Ingredients are the items used to make the product, while the formula provides details around how the ingredients are used in making the product.**

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	patients with information about the ingredients in their compounded medicine will support patient choice and safer patient outcomes. **Do you agree that the formula for their compounded medicine must be provided when requested by the patient? Why or why not?**	**It is not clear whether the aim of this change in guidance is to provide a list of ingredients to assist in identifying, e.g., allergens, additives, *etc.*, or whether the intent is to support a transition of care between facilities/pharmacies, through the provision of the whole formula.** **A list of ingredients to support allergen identification is certainly supportable and should be made available to patients upon request. However, consideration should be given as to the practicalities of doing this where a compounded product may use a proprietary base product within the formula. For example, products such as Ora-Plus, or Ora-Sweet, are commonly used suspending bases. Does an ingredient list just need to specify the base product used, or does it need to outline the ingredients in any proprietary products as well? Do the ingredient lists just need to state ingredient, or should they reflect quantity/percentage of ingredient as well? Will manufacturers of proprietary base products be willing to share their formula/ingredient lists to support this requirement? Do pharmacies have the option of charging an administrative fee to support the development of these ingredient lists?** **Will software providers be required to provide reports that support this functionality, i.e. will ingredient lists be able to be printed on a secondary label to attach to the back of the compounded product? Or will pharmacies need to develop an ingredient fact sheet – if so, is there a preferred format?** **The sharing of formula is more complicated. Whilst the intent of making safe compounded products available across transitions of care is supportable, some pharmacies invest heavily into the development of these formula, this includes not only time, but access to specific and costly references and subscriptions to support this function. It becomes a disincentive to invest into safe and appropriate formulae development when it is a requirement to then give this away to a competitor. This may result in less well-researched formula, where there is a disincentive to invest resource in the development and research of formulae.**
3	The revised compounding guidelines include content that is specific to medicines compounded for animal patients.	**Nil comment**

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	Is the new content that is specific to medicines for animal patients clear and helpful? Why or why not?	
4	**Is there any content that needs to be changed, added or deleted in the revised guidelines? If so, please provide your suggestions and reasons.**	**The current requirements around risk assessments should be reviewed to provide a more practical approach. A full risk assessment should be undertaken when a new item is first compounded. However, on subsequent repeats of that item, or even when the same product is compounded for a new patient, there are aspects of the risk assessment that will not change (for example, environmental risk factors), and hence an abbreviated risk assessment could be undertaken.**
5	**Is the language of the revised guidelines clear and is the structure helpful? Why or why not?**	**The term 'simple' compounding is inappropriate and does not reflect the skill involved, the technical knowledge, or importance of this function. It is suggested that instead of referring to 'simple' and 'complex' compounding, the guideline should refer to compounding and complex compounding.** **The guideline also uses the terms ingredients and formula interchangeably – this is confusing as the 2 terms have differing meanings.**
6	**Please provide any other feedback about the revised guidelines.**	**The main impact of these guidelines will be on patients; there is potential that rather than improve access to efficacious and safe medications it will reduce access, as fewer pharmacies will choose to specialise in compounding. In addition, these guidelines will likely increase the cost of accessing treatments for many patients. The cost of imported medicines through SAS, and other schemes is unregulated, and importers will soon understand that there is a dedicated market and limited supply.** **There is a risk that some treatment options may no longer be available through community pharmacy especially (or only through specialist compounders at a much higher price – this was seen in the UK with Rosemont pharmaceuticals).** **Limited access to products within the community sector may place increased pressure on acute hospitals to fill this gap. Not only will this**

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		increase pressure on hospital pharmacy departments in terms of workload but will have a budgetary impact, as well as equity of access. Section 5.3 refers to modifying commercial medication (e.g., crushing tablets) and this modification needs to be recorded on the script. Given this is a PBA guideline, it is assumed this guidance on altering the prescription is an action the pharmacist should undertake. The legalities of the pharmacist altering the legal order/prescription in this way are unclear. The implications of a script altered by a pharmacist around any PBS requirements and claiming are also unclear. Whilst the intent of ensuring informed patient consent is supportable, there needs to be more guidance around how this can be done effectively in this setting. Patient literacy and consent will be a complex area to manage for some patients whose medication is required to change, and they may not understand, or be happy with a change, especially if it costs them more. Pharmacists may require some support and guidance in the best way to articulate the risks involved with compounded products compared to alternative treatment options. Prescribers should also have a role in this process. The prescriber is best placed to explore many of these issues with the patient, as they are the ones who can detail the options they are willing to consider prescribing, with the patient. In many circumstances, the pharmacist is not in a great position to offer alternative treatment modalities, as they cannot know what the prescriber will consider acceptable at the time of consent. Additionally, the pharmacist may also not be privy to the extent of disease being managed to fully consent the patient to the risks of not accepting the treatment. Pharmacists need more guidance on how to practically achieve informed consent in this setting, and what their professional obligations are, should a patient elect to not accept treatment following the consenting process. It can be time consuming to locate suitable imported products, and pricing may fluctuate greatly. There should be guidance provided around accessing a suitable of the product (i.e., labelling and Product Information available in English, which jurisdictions have comparable

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		Safety & Quality oversight of therapeutic products, which are less likely to be impacted by counterfeiting, etc.). **In addition, there are ongoing issues with consistent access to safe overseas products, and importers frequently change between products offered as a result of insecure supply chains, particularly with some countries placing export bans on therapeutic products. There is a need for guidance in understanding how to safely transition patients between differing imported products when bioavailability is not known, and in the context of varying patient understanding and literacy. In some clinical settings, it may be appropriate to swap between a 50mg/mL and 100mg/mL product. In other settings (such as narrow Therapeutic Index drugs, highly sensitive disease state, or a patient who is easily confused) this may not be appropriate or safe.** **A further consideration is that this guidance is only applicable to pharmacists. Where a pharmacist exercises their professional duties and refuses to compound, or modify a product, based upon these guidelines, there is a risk that other clinicians (prescribers or nurses) may elect to undertake this role. There is currently a dearth of guidance for those professions in exercising their professional responsibilities in this space. The risk here is that compounding practice is driven into less safe and less regulated practice. These guidelines should be shared with other AHPRA Boards for consideration of broader health professional application.** **The guidelines permit for unscheduled, schedule 2 and schedule 3 medicines to be compounded at patient's request, without a prescription/order from an authorised prescriber. Further guidance is required with how this should be applied for products that sit across multiple schedules (i.e., products that are in schedule 2, 3, and 4).**
7	The Board proposes to retire the *Professional practice profile* for pharmacists undertaking complex compounding, as a professional practice profile should be practitioner specific, describe an individual's scope of practice and is not common to all pharmacists undertaking complex compounding. Individuals should develop their own practice	**Individual professional responsibility is key; there is a risk in that leaving up to individuals/organisations potentially with commercial interest in the area maybe more "flexible" in their interpretations. This may also create issues with organisations/businesses pressuring staff to undertake practice that the individual has deemed un-professional. Ideally, there should be a minimum set of expectations outlined which are considered**

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	profile by selecting the relevant competencies from the competency standards and customising them for use in their own practice setting. **Do you agree with the Board's proposal to retire the currently published *Professional practice profile* for pharmacists undertaking complex compounding? Why or why not?**	**necessary to demonstrate basic competence (i.e., outlines expected minimum education requirements and which reference text are deemed essential). Without detailing minimum standard, this creates risk for individuals in interpretation and application.** **The PBA may consider partnering with professional organisations, such as PSA and SHPA, to provide further contemporary guidance in this space to deliver up-to-date professional practice expectations and training to complement this guideline.**
8	The Board developed the fact sheet to provide helpful context for members of the public and support their participation in this consultation. **Should the Board publish the fact sheet on its website for pharmacists and members of the public to access? Why or why not?**	**Whilst increased patient access and understanding is a positive thing, it is difficult to understand how this will be implemented in practice. For example, how does a patient assess/understand the response from a pharmacist with respect to their educational requirements and study completion in this space?** **There needs to be a clear aim for the messages intended to be delivered in this fact sheet and to be delivered in a way that does not undermine the pharmacist's professional role/judgment, or drive conflict.**