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: _____Medisca Australia_____

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?**	Medisca requests that the new definition of 'commercial medicine' as "a medicine that can be accessed in Australia through any pathway for the lawful supply of medicines...includ[ing] medicines on the ARTG and medicines accessed via pathways such as s19A, Special Access Scheme and others" be removed. Commercially available medications have long been understood to mean those medications approved by the TGA and listed on the ARTG. Redefining this term will cause confusion within pharmacies and regulatory bodies and may have sweeping long term ramifications on the market of finished drug products in Australia. The Pharmacy Board of Australia and the Medical Board of Australia Joint Statement on Compounded Medicines (here) states that a compounded medication should only be prescribed if an appropriate commercial product is unavailable or a commercial product is unsuitable. They go on to state that "A pharmacist who receives a request to prepare a compounded medicine for which there is a close formulation to a suitable medicine **on the ARTG** and which is unlikely to produce a different therapeutic outcome to **the ARTG medicine** should consult with the prescribing medical practitioner regarding alternative treatment options." Also "understand that unlike medicines **on the ARTG**, compounded medicines have not been assessed by the TGA for efficacy, quality and safety." It is clear that the PBA and MBA have traditionally only considered those products listed on the ARTG as commercial products as products imported under SAS or s19a have also not been assessed by the TGA. Additionally, in the previous PBA Guidelines on Compounding of Medicines (revised 2017) under "15. Counselling and Information for Patients" it is explained that the pharmacist must counsel the patient including "an explanation of why a compounded product is being supplied, and how this differs to a **commercially-available medicine which requires the manufacturer to meet the requirements of the TGA for addition of medicines to the**

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		Australian Register of Therapeutic Goods". Again, recognizing that commercially available medicine only refers to those medicines listed on the ARTG. Again in a 2020 FAQ on compounded medicines (here) published by PBA, the PBA states that "For the purposes of the Board's guidelines, 'commercial product 'and 'commercially available 'refer to medicines that are listed on the Australian Register of Therapeutic Goods (ARTG) that are able to be accessed by pharmacists via a wholesaler or directly from the manufacturer." This new definition is also in **direct opposition** to TGA guideline for sponsors of SAS medication (here)which states, the **SAS should not be used when "Medicines (other than medicinal cannabis) are extemporaneously compounded by a pharmacist for the treatment of a particular patient.**" Since the safety of unregistered and unapproved medication accessed via SAS has not been assessed by TGA, it is clear that TGA does not recognize them as superior treatment when medication could extemporaneously be compounded by a pharmacist for treatment of a particular patient. This is likely due to the fact that the raw material used by compounding pharmacists, are sourced from TGA licensed suppliers, regulated by TGA. Compounding pharmacists in Australia also adhere to guidelines outlined by TGA (under the relevant exemptions to therapeutic goods legislation), PBA, APF, QC2020, Safe Work Australia and if applicable the guidelines specific to the council of pharmacy and health departments in their jurisdiction. This is not true for products imported under SAS and s19A. While we know the country where the final dosage form is manufactured, we do not know that the starting components meet the standards outlined by the TGA as is the case with compounded product. Even here we have heard reports of imported product arriving with the packaging, product information leaflet and CMI in languages other than English raising concerns regarding patient safety. How could the

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		pharmacists verify the authenticity of medication, verify the ingredients or provide sufficient reliable information to patient in their counselling? If SAS medications are not regulated by TGA, how could a translation provided by sponsor be validated or verified? Finally we have concerns that by redefining "commercially available" to include products imported under SAS and s19a will undermine the TGA and ARTG process and may have long-term unforeseen consequences. This change would recognize imported product as commercially available and could set a new precedent that would disincentivise manufacturers from going through the costly but necessary steps to ensure their product meets the standards set by the TGA. We are concerned that this redefinition has not been thoroughly vetted with other affected agencies such as the MBA and TGA and would negatively impact patient safety and care. We ask that it be removed and SAS and S19a product remain as unapproved medications which are not "commercially available".
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 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?**	Medisca requests clarity regarding the requirements for disclosing the "ingredient information" of compounded medication. Under 'Ingredient Information', the document states: "A patient using a compounded medicine **should have access to a list of ingredients**, as with a commercial medicine. Providing patients with information about the ingredients in their compounded medicine will support patient choice and safer patient outcomes. If a pharmacist wishes to have proprietary **ingredient formulations** such as a cream base or a flavour, this is regulated by the TGA." Medisca agrees that all ingredients should be disclosed to a patient upon request, including concentrations of Active Pharmaceutical Ingredients and any ingredients that are part of a proprietary base and/or flavor contained in the dispensed, compounded product. We are concerned that the wording could be misconstrued to mean that a compounding pharmacy must share their

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		"formulation". Formula refers to concentration of excipients and specific preparatory instruction. Many pharmacies pay for access to the information contained in the formula which are often considered intellectual properties of the organizations or stakeholders. Distributing formulas which are not open for public access or distribution due to copyright, is breach of copyright restriction. Sharing this information would do nothing to increase patient safety but could result in backdoor access to sensitive business information. We ask that the above paragraph be replaced with: "A patient using a compounded medicine should have access to a list of ingredients, as with a commercial medicine. This includes ingredient lists of any proprietary products (such as bases or flavours) used as components in the compounded medicine. Providing patients with information about the ingredients in their compounded medicine will support patient choice and safer patient outcomes."
3	The revised compounding guidelines include content that is specific to medicines compounded for animal patients. **Is the new content that is specific to medicines for animal patients clear and helpful? Why or why not?**	Yes, Medisca agrees that information provided are clear and helpful. Medisca suggests changing "type" of animal to "species".
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.**	As discussed in question 1, Medisca suggests changing the definition of "commercially available medicine" to what has been previously known including "medicines on ARTG" and exclude unapproved medications which could be accessed via SAS and S19A from the definition of "commercially available medicine".
5	**Is the language of the revised guidelines clear and is the structure helpful? Why or why not?**	Yes.

	Question	Your feedback (include guideline number/section)
6	**Please provide any other feedback about the revised guidelines.**	Medisca appreciates the diligent efforts of the board in addressing our concerns in the previous version of the guidelines, particularly regarding the removal of USP 800 from the proposed draft and allowing compounding pharmacists the necessary flexibility to exercise their professional judgment. Medisca would like to express our sincere gratitude to the Board for fostering collaboration with the industry and granting stakeholders the invaluable opportunity to provide feedback on this crucial document. Recognizing its potential impact on patient health and the pharmacy business landscape throughout Australia, we commend your commitment to ensuring a comprehensive and inclusive process.
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 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?**	Yes. Medisca agrees with Board to retire the currently published Professional Practice Profile.
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?**	Medisca would like clarification on: 1- How will the new guideline be communicated with pharmacists? 2- Will there be any communication with prescribers regarding the new guidelines? 3- Will there be a grace period allowing the pharmacists to make arrangements in order to adhere with new guidelines? Updating the current FAQ on compounding medicines and recorded webinars on new guidelines would highly be appreciated by pharmacists.

Address Unit 7, Heritage Business Park
5-9 Ricketty Street, Mascot
NSW 2020 Australia
Toll Free 1300 786 392
Fax +61 2 9700 9047
www medisca.com.au

Date 24/07/2023
Subject Response to Guidelines on compounding of medicines review
Recipient Pharmacy Board of Australia

We at Medisca Australia, hereby submit our formal response to the open public comment period on the draft revised PBA Guidelines on compounding of medicines.

Medisca Australia has established itself as a leading entity within the pharmaceutical compounding industry. Renowned for our innovative and entrepreneurial spirit, we have earned a solid reputation for delivering unparalleled quality ingredients, compounding products, and supplies, accompanied by exceptional service and educational support tailored to compounding pharmacists. Our unwavering dedication lies in staying abreast of regulatory changes, adhering to the highest standards of practice, and closely monitoring emerging trends in the healthcare industry. By diligently imparting our knowledge to clients, we strive to serve as an invaluable resource center for the pharmaceutical compounding community, empowering pharmacists with the necessary tools and expertise to excel in their practice.

Medisca appreciates the diligent efforts of the board in addressing our concerns in the previous version of the guidelines, particularly regarding the removal of USP 800 from the proposed draft and allowing compounding pharmacists the necessary flexibility to exercise their professional judgment.

Medisca would like to express our sincere gratitude to the Board for fostering collaboration with the industry and granting stakeholders the invaluable opportunity to provide feedback on this crucial document. Recognizing its potential impact on patient health and the pharmacy business landscape throughout Australia, we commend your commitment to ensuring a comprehensive and inclusive process and offer the following feedback:

Request:

Medisca requests that the new definition of ‘commercial medicine’ as “a medicine that can be accessed in Australia through any pathway for the lawful supply of medicines…includ[ing] medicines on the ARTG and medicines accessed via pathways such as s19A, Special Access Scheme and others” be removed.

Rationale:

Commercially available medications have long been understood to mean those medications approved by the TGA and listed on the ARTG. Redefining this term will cause confusion within pharmacies and regulatory bodies and may have sweeping long term ramifications on the market of finished drug products in Australia.

The Pharmacy Board of Australia and the Medical Board of Australia Joint Statement on Compounded Medicines (here) states that a compounded medication should only be prescribed if an appropriate commercial product is unavailable or a commercial product is unsuitable. They go on to state that "A pharmacist who receives a request to prepare a compounded medicine for which there is a close formulation to a suitable medicine **on the ARTG** and which is unlikely to produce a different therapeutic outcome to **the ARTG medicine** should consult with the prescribing medical practitioner regarding alternative treatment options." Also "understand that unlike medicines **on the ARTG**, compounded medicines have not been assessed by the TGA for efficacy, quality and safety." It is clear that the PBA and MBA have traditionally only considered those products listed on the ARTG as commercial products as products imported under SAS or s19a have also not been assessed by the TGA.

Additionally, in the previous PBA Guidelines on Compounding of Medicines (revised 2017) under "15. Counselling and Information for Patients" it is explained that the pharmacist must counsel the patient including "an explanation of why a compounded product is being supplied, and how this differs to a **commercially-available medicine which requires the manufacturer to meet the requirements of the TGA for addition of medicines to the Australian Register of Therapeutic Goods**". Again, recognizing that commercially available medicine only refers to those medicines listed on the ARTG.

Again in a 2020 FAQ on compounded medicines (here) published by PBA, the PBA states that "For the purposes of the Board's guidelines, 'commercial product 'and 'commercially available 'refer to medicines that are listed on the Australian Register of Therapeutic Goods (ARTG) that are able to be accessed by pharmacists via a wholesaler or directly from the manufacturer."

This new definition is also in **direct opposition** to TGA guideline for sponsors of SAS medication (here)which states, the **SAS should not be used when** "**Medicines (other than medicinal cannabis) are extemporaneously compounded by a pharmacist for the treatment of a particular patient.**" Since the safety of unregistered and unapproved medication accessed via SAS has not been assessed by TGA, it is clear that TGA does not recognize them as superior treatment when medication could extemporaneously be compounded by a pharmacist for treatment of a particular patient.

This is likely due to the fact that the raw material used by compounding pharmacists, are sourced from TGA licensed suppliers, regulated by TGA. Compounding pharmacists in Australia also adhere to guidelines outlined by TGA (under the relevant exemptions to therapeutic goods legislation), PBA, APF, QC2020, Safe Work Australia and if applicable the guidelines specific to the council of pharmacy and health departments in their jurisdiction. This is not true for products imported under SAS and s19A. While we know the country where the final dosage form is manufactured, we do not know that the starting components meet the standards outlined by the TGA as is the case with compounded product. Even here we have heard reports of imported product arriving with the packaging, product information leaflet and CMI in languages other than English raising concerns regarding patient safety. How could the pharmacists verify the authenticity of medication, verify the ingredients or provide sufficient reliable information to patient in their counselling? If SAS medications are not regulated by TGA, how could a translation provided by sponsor be validated or verified?

Finally we have concerns that by redefining “commercially available” to include products imported under SAS and s19a will undermine the TGA and ARTG process and may have long-term unforeseen consequences. This change would recognize imported product as commercially available and could set a new precedent that would disincentivise manufacturers from going through the costly but necessary steps to ensure their product meets the standards set by the TGA.

We are concerned that this redefinition has not been thoroughly vetted with other affected agencies such as the MBA and TGA and would negatively impact patient safety and care. We ask that it be removed.

Request:

Medisca requests clarity regarding the requirements for disclosing the “ingredient information” of compounded medication

Rationale:

Under ‘Ingredient Information’, the document states: “A patient using a compounded medicine **should have access to a list of ingredients**, as with a commercial medicine. Providing patients with information about the ingredients in their compounded medicine will support patient choice and safer patient outcomes. If a pharmacist wishes to have proprietary **ingredient formulations** such as a cream base or a flavour, this is regulated by the TGA.”

Medisca agrees that all ingredients should be disclosed to a patient upon request, including concentrations of Active Pharmaceutical Ingredients and any ingredients that are part of a proprietary base and/or flavor contained in the dispensed, compounded product. We are concerned that the wording could be misconstrued to mean that a compounding pharmacy must share their “formulation”. Formula refers to concentration of excipients and specific preparatory instruction. Many pharmacies pay for access to the information contained in the formula which are often considered intellectual properties of the organizations or stakeholders. Distributing formulas which are not open for public access or distribution due to copyright, is breach of copyright restriction. Sharing this information would do nothing to increase patient safety but could result in backdoor access to sensitive business information. We ask that the above paragraph be replaced with:

“A patient using a compounded medicine should have access to a list of ingredients, as with a commercial medicine. This includes ingredient lists of any proprietary products (such as bases or flavours) used as components in the compounded medicine. Providing patients with information about the ingredients in their compounded medicine will support patient choice and safer patient outcomes.”

Thank you for your consideration. If you have any questions please reach me at [redacted]

Sincerely,

Sara Monfared
Compounding Pharmacist and Training Facilitator

Medisca

References:

Pharmacy Board of Australia. (2017. November 24) Joint statement on compounded medicines - Pharmacy Board of Australia and Medical Board of Australia.

Pharmacy Board of Australia (2020. January 16). FAQ for pharmacists on the Compounding of Medicines.

Therapeutic Goods Administration (2023. March) Special Access Scheme (SAS) Guidance for Sponsors