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: Novartis Pharmaceuticals Australia Pty Limited

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?**	Novartis agrees with the proposed changes to the compounding guidelines. The details on the medicine supply pathways to consider before deciding if it is appropriate to compound a medicine are clear and explicit which is welcomed by Novartis. There is clarity on the role of the TGA in providing public assurance on the quality, safety and efficacy of registered medicines. There is also explanation of alternate ways in supplying unregistered medicines that are not available in Australia (that may be available overseas eg) or under evaluation by TGA. The pathways are explained as SAS, AP scheme and importation/supply for use in a clinical trial. In particular, there is now clear guidance on when it may be appropriate to compound a medicine by inclusion of the following: Medicines should only be compounded in circumstances when: a. an appropriate commercial medicine does not exist, is unavailable or cannot be accessed within the timeframe that the medicine is required for use by the patient, or b. a commercial medicine is unsuitable (for example, if a patient has a known allergy to an excipient in the medicine or the dose forms available are unsuitable) c. required for the purpose of research sanctioned by a recognised human research ethics committee A medicine (whether prescribed by an authorised prescriber or not) should not be compounded if: a. a commercial medicine is a suitable treatment option for the patient, or b. the compounded medicine would be a close formulation to that of an available and suitable commercial medicine, or combination of commercial medicines, and is unlikely to produce a different therapeutic outcome, or c. a commercial medicine becomes available, is suitable and can be accessed within the timeframe that the medicine is required for use by the patient. If a suitable commercial medicine (or combination of commercial medicines), is available, a pharmacist must not: a. offer to compound the medicine, including if the medicine can be compounded at a lower price than the available commercial medicine, or b. compound a slightly different medicine that is unlikely to produce a different therapeutic outcome

	Question	Your feedback (include guideline number/section)
		We also understand that these revised Guidelines on compounding of medicines are covered under National Law (rather than practice guidelines developed by professional associations). Novartis welcomes the clarity on the regulatory framework in Australia as well as the clarity on when medicines should and should not be compounded.
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?**	Novartis agrees the formula for the compounded medicine must be provided when requested by the patient and in fact should be provided in any case. This is consistent with commercial prescription medicines where the active and inactive ingredients are listed in the CMI.
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?**	This is clear and helpful.
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.**	Revised guidelines are clear and explicit particularly with reference to when medicines should and should not be compounded.
5	**Is the language of the revised guidelines clear and is the structure helpful? Why or why not?**	Yes the language is clear and the structure appropriate.
6	**Please provide any other feedback about the revised guidelines.**	Explicit details on compounding practices within Australia are clear and welcomed by Novartis (and we believe other sponsors) invested in research and development.

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		Another note regarding quality of compounding is around GMP. As GLP rather than GMP is required in the compounding setting, the use of a commercial product where available provides greater quality assurance of the end product. Namely, under GMP; the facilities must have the appropriate sterilisation procedures, equipment, training, method validation, continuous improvement plans etc. that are all subject to routine inspection to the PIC/S standard. Institutional protocols by contrast could vary quite considerably from this standard and among each other. GMP production and having sites that adhere to it creates predictability in the finished good supplied. • [Products] manufactured by pharmaceutical companies undergo the strict and highly regulated quality control processes under Good Manufacturing Practices (GMP). Locally compounded formulations are not subject to the same requirements • Locally compounded formulations do not receive Therapeutic Goods Administration (TGA) approval and they are subject to Good Laboratory Practices (GLP), which are intended for the **non-commercial production** of end use products and differ from GMP standards.
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?**	The *Professional practice profile* for pharmacists undertaking complex compounding may still be helpful for those involved.
8	The Board developed the fact sheet to provide helpful context for members of the public and support their participation in this consultation.	Novartis believes the Board should publish the fact sheet on its website for pharmacists and members of the public to access to provide transparency on compounding practices in Australia. The fact sheet will provide explicit information on when medicine compounding is and is not allowed. If a

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	Should the Board publish the fact sheet on its website for pharmacists and members of the public to access? Why or why not?	commercial medicine is available then compounding should not take place. Patients and the general public will be able to have a greater understanding and make informed choices and decisions.