Pharmacy Council of New South Wales

Protecting the public
Regulating pharmacists and pharmacies

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Fact sheet

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Raw materials used in compounding

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A number of complaints relating to the authenticity of raw materials (ingredients) used in compounded preparations have been brought to the attention of the Council. This fact sheet seeks to clarify pharmacists' obligations with respect to raw materials used in compounding.

- All raw materials used should comply with pharmacopoeial standards and be produced by acceptable manufacturers.
- A Certificate of Analysis should not be solely relied upon to assess the suitability of raw materials. Where one is not available or not provided by the manufacturer, or appears dubious, pharmacists should have raw materials independently tested to confirm their compliance with pharmacopoeial standards prior to use in compounding.
- Where there is a need for independent testing of raw materials, testing should be conducted by a laboratory holding appropriate accreditation for testing e.g. issued by the National Association of Testing Authorities (NATA) or the Therapeutic Goods Administration (TGA).
- When sourcing raw materials via a supplier or third-party, pharmacists are still responsible for ensuring the original manufacturer engaged by the supplier or third-party is acceptable.
- When procuring raw materials, pharmacists must consider whether the manufacturer has implemented appropriate controls for the manufacture of the raw materials, and has effective processes in place to assure the quality of the raw materials supplied.
- In Australia, acceptable manufacturers of active pharmaceutical ingredients will hold a **manufacturing licence** for the manufacture of a particular raw material from the TGA.
- Overseas manufacturers will hold certification relevant to the manufacture of raw materials, e.g. a certificate of Good Manufacturing Practice (GMP) compliance or equivalent accreditation from a regulatory or accrediting authority equivalent to the TGA.
- Suppliers/wholesalers/third-party distributors of raw materials that do not undertake steps in the manufacture of APIs, are not required to hold a manufacturing licence issued by the TGA for the supply/wholesale or distribution of raw materials.

Refer to the *Manufacturer assessment flowchart* in this document and the *Extemporaneous dispensing* section in the current edition of the *Australian Pharmaceutical Formulary and Handbook* for further information.

A wholesale licence or an import licence (which some suppliers may hold) is not relevant in determining the quality of the raw materials produced or the acceptability of the manufacturer.

Case study A:
A pharmacist purchased an antibiotic raw material from an unknown overseas supplier which she found through an internet search. The raw material was seized by the Australian Border Force and when tested, the substance was found to be different to the one ordered and specified on the label. When dealing with unknown suppliers and manufacturers, all batches of materials will need to be independently tested to confirm identity, purity and conformity against pharmacopoeial standards (e.g. BP, USP or PhEur). Had the raw material not been tested and used in compounding, any recipient of the compounded product incorporating the raw material may have come to harm.

Case study B:
A pharmacist purchased a raw material from a reputable supplier which was used in a compounded preparation. Adverse reactions were reported and upon investigation, the pharmacist advised he had no knowledge of the original manufacturer as he had relied on the supplier. While the supplier may have been reputable, the pharmacist was still responsible for determining whether the raw material complied with pharmacopoeial standards and that the **original manufacturer** and any information/documentation provided was acceptable. As little was known about the original manufacturer, independent testing was needed to confirm identity, purity and conformity against pharmacopoeial standards (e.g. BP, USP or PhEur).

For more information on your obligations when compounding medicines, the Pharmacy Board of Australia has issued *Guidelines on compounding of medicines*. These guidelines may be used in disciplinary proceedings under the Health Practitioner Regulation National Law, as it applies in each Australian state and territory, as evidence of what constitutes appropriate professional conduct or practice for pharmacists.

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Manufacturer assessment flowchart

Raw materials (ingredients) should be produced by acceptable manufacturers. Refer to the *Extemporaneous dispensing* section in the *Australian Pharmaceutical Formulary and Handbook* for further information.