Pharmacy Council of New South Wales

Protecting the public
Regulating pharmacists and pharmacies

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Frequently Asked Questions (FAQs) for the Fact sheet – Raw materials used in compounding

September 2018

These FAQs should be read in conjunction with the Council's *Fact sheet - raw materials used in compounding.* It provides pharmacists with additional information on their obligations for raw materials used in compounding and has been developed in response to queries and feedback received by Council.

1. **Why was the *Fact sheet - Raw materials used in compounding* (Fact sheet) published?**

   The Fact sheet was developed as a **resource** for pharmacists to support their decision making process when procuring raw materials for compounded preparations. Other references that should be consulted include the Pharmacy Board of Australia's *Guidelines on compounding of medicines* and the current edition of the Pharmaceutical Society of Australia's *Australian Pharmaceutical Formulary and Handbook.* Ultimately, it is the responsibility of the pharmacist to determine whether a raw material is acceptable and appropriate for use in compounded preparations. **The Council does not provide specific advice on individual cases/circumstances.**

2. **Who was involved in the development of the Fact sheet?**

   The Fact sheet was developed in consultation with the Pharmacy Board of Australia, the Therapeutic Goods Administration (TGA) and the Pharmaceutical Society of Australia. No commercial organisations involved in the manufacture or sale of raw materials were involved in the development of the Fact sheet. **The Council does not endorse specific manufacturers, suppliers, wholesalers or third-parties.**

3. **Why do I have to comply with quality standards? As a compounding pharmacist I am practising under an exemption in the Therapeutic Goods legislation.**

   The *Therapeutic Goods Regulations 1990 (Cth)* provides specific exemptions with respect to the manufacturing, registration and listing of therapeutic goods which allow pharmacists to compound medicines in certain circumstances. However, the exemptions in the *Therapeutic Goods Regulations 1990 (Cth)* do not apply to quality standards. **Compounded medicines must meet quality standards set in the *Therapeutic Goods Act 1989 (Cth).*** See the Pharmacy Board of Australia's *Background on the regulation of compounding by pharmacists* for further information.

4. **Do I need to conduct independent testing for each delivery of raw material?**

   The testing of raw materials is not normally required where the pharmacist is able to determine that the raw material originates from a domestic or overseas manufacturer that holds current accreditation from the TGA or equivalent overseas regulatory authority, and a **genuine** Certificate of Analysis demonstrating that the material complies with the relevant quality standards is provided - for each batch received.

   Independent testing, to verify that the materials comply with pharmacopoeial standards, should be conducted by an appropriately accredited laboratory where there is any uncertainty about the supply chain, source or quality of a raw material.

5. **I have been advised by a manufacturer that they have a TGA licence to manufacture. Is this sufficient?**

   Australian manufacturers of active pharmaceutical ingredients (APIs) can be identified by searching www.ebs.tga.gov.au**.**

   The Fact sheet stipulates that in Australia, acceptable **manufacturers** of APIs will hold a manufacturing licence from the TGA **for the manufacture of particular raw material(s)**.

The manufacturing licence will detail the steps in the manufacturing process the manufacturer is licensed to carry out (e.g. repackaging, labelling etc.) and is only applicable to materials manufactured under the terms of the licence. To determine whether the manufacturing licence **applies to the raw material procured**, contact your manufacturer. They should be able to provide details of where the product was manufactured and/or sourced from.

E.g. Company X holds an Australian manufacturing licence. A pharmacist wishes to purchase **cephalexin** from company X. Upon further investigation, the manufacturing licence applies to amoxicillin, and not cephalexin, which Company X imports from an overseas manufacturer. In this instance, Company X is acting as a **supplier/wholesaler/third-party** for the supply of cephalexin, is not the manufacturer of the cephalexin, and therefore should be assessed as a **supplier/wholesaler/ third-party** under the *Manufacturer assessment flowchart* on page two of the Fact sheet.

6. Do third-party suppliers, distributors and/or wholesalers need to hold a manufacturing licence from the TGA to supply raw materials to pharmacists?

A licence to manufacture from the TGA is only required by persons or companies undertaking steps in the manufacture (e.g. extraction, synthesis, isolation, purification, packaging, labelling, and testing) of an API. Third-party suppliers, distributors and wholesalers that are not undertaking any step in the manufacture of an API are not required to hold a *licence to manufacture* from the TGA to supply raw materials.

A wholesale licence is a separate matter. Any wholesale distributor of scheduled APIs must be licensed by the jurisdiction in which they operate.

7. With respect to the *Manufacturer assessment flowchart* on the second page of the Fact sheet:

a. How can I tell if a Certificate of Analysis is genuine?

The compounding pharmacist is accountable for all stages of the compounding process, including the risk assessment of raw materials used.

A Certificate of Analysis (C of A) should not be solely relied upon to assess the suitability of a raw material. In determining whether a C of A is genuine, this should be done in the context of the pharmacist's assessment of the suitability of the manufacturer. Indicators of a high risk manufacturer may include:

- pricing that is significantly out of range when compared to other manufacturers,
- stock availability of a raw material when many other manufacturers are out of stock,
- manufacturers found on dubious internet websites, and
- irregularities in C of As provided (e.g. C of As not in English, batch number does not correspond to order, inconsistent letterhead, invalid date of issue).

If due diligence on the manufacturer has been conducted, and it is the pharmacist's conclusion that the manufacturer is acceptable, then the pharmacist should be reasonably satisfied that the C of A provided by the manufacturer is genuine.

b. How can I tell if an overseas manufacturer is 'most likely acceptable'?

An overseas manufacturer will hold a certificate of Good Manufacturing Practice (GMP) compliance or equivalent accreditation from a regulatory or accrediting authority of equivalent standing to the TGA.

The TGA website, which provides an overview of international agreements and arrangements for GMP clearance, can provide an indication of equivalent accreditation from a regulatory or accrediting authority equivalent to the TGA. Go to https://www.tga.gov.au/international-agreements-and-arrangements-gmp-clearance

The TGA has a cooperation agreement with the United States Food and Drug Administration (USFDA). USFDA approval of API manufacturing facilities is normally acceptable to the TGA providing the inspection was performed using a comparable GMP standard, e.g. ICH Q7.

c. If an overseas manufacturer is considered 'most likely acceptable' as per the flowchart, who is responsible for making 'additional investigations'?

The compounding pharmacist.

d. **If an overseas manufacturer is considered 'most likely acceptable' as per the flowchart, what additional investigations may be appropriate?**

Examples of additional investigations that may be appropriate include:

- Ensuring the delivery note corresponds to the raw material ordered,
- Doing a visual inspection of the raw material to determine whether the integrity of the packaging has been maintained and the seal is intact at the time of delivery, and
- Investigating damage to containers and any other problems which may adversely affect the quality of the material. Any issues should be satisfactorily resolved before use in compounded preparations.

e. **I have made independent enquiries regarding a manufacturer and I am still not confident that the raw material is safe to use in my compounded preparation. What should I do?**

If a pharmacist is in any doubt regarding the quality of a raw material or the acceptability of a manufacturer, independent testing prior to use is needed to confirm identity, purity and conformity against pharmacopoeial standards (e.g. BP, USP or PhEur). Testing may be conducted by a laboratory holding appropriate accreditation for testing. Laboratories must be equipped to conduct the required tests to confirm identity, purity and conformity against pharmacopoeial standards (e.g. BP, USP or PhEur) and hold accreditation against *ISO 17025 General requirements for the competence of testing and calibration laboratories.*