

Compounding in community pharmacy

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When a drug is not available, or is unavailable in a form suitable for a particular patient, compounding may provide a solution to the individual's needs. Compounding is 'the preparation and supply of a single unit of a product intended for immediate use by a specific consumer'.¹ It is also known as extemporaneous dispensing. Compounding may involve modification of a manufactured product or the preparation of a compound from raw ingredients. Although most often associated with pharmacists, other practitioners such as naturopaths and herbalists may compound products.

All medicines were compounded until the expansion and mechanisation of the pharmaceutical industry led to the availability of mass-manufactured drugs. Although now practised to a lesser extent by most pharmacists, compounding is still taught as part of the pharmacy curriculum. All community pharmacies are required to maintain basic compounding equipment for the provision of this service.

Based on experience in the USA where compounding is widely promoted, requests for individualised dosage forms are likely to become more frequent to meet the specific needs of individual patients (see box).

In this issue...

Corticosteroids are effective drugs, but can have serious adverse effects such as osteoporosis. Evange Romas advises on how to limit the loss of bone in patients taking long-term corticosteroids.

Ear drops are commonly prescribed in general practice, but may contain ototoxic drugs. Harvey Coates explains how to reduce the risk of ototoxicity when managing discharging ears.

Some ear drops are not available as commercial preparations and this is where a compounding pharmacy can help. However, Mark Feldschuh tells us that there have been concerns about some of the products that are being compounded.

Some medicines bought from pharmacies can impair driving skills, but Olaf Drummer says that alcohol and illicit drugs remain the biggest threats to road safety.

Which medicines are compounded?

Manufactured medicines are preferable to compounded products as their production is governed by the 'Code of Good Manufacturing Practice for Medicinal Products' and they undergo evaluation by the Therapeutic Goods Administration (TGA). However, many medicines are unavailable in suitable forms for particular patients. The size of the Australian market precludes registration of products required for small but significant patient populations and many products are discontinued or unavailable for economic rather than safety reasons.²

Compounding is often needed for paediatric patients. In a review of all products with approved paediatric indications, around 24% were not available in a form suitable for administration to children.³ The problem of balancing vitamin D deficiency and exposure to sunlight has led to requests to compound high doses of vitamin D as the commercially available products contain insufficient quantities.^{4,5} Metronidazole vaginal gel for the treatment of bacterial vaginosis is an example of a manufactured product available overseas that must be compounded by a pharmacist if required by an Australian patient.⁶ More controversially, there has been an increase in the prescribing of so-called 'natural' bioidentical hormones following concerns about the risks of hormone replacement therapy with synthetic oestrogen and progestogen.

Compounding concerns

The Therapeutic Goods Regulations 1990 exempt compounded products from registration by the TGA if they 'are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person' and they are prepared in a pharmacy 'for supply (other than by wholesale) on or from those premises'. Due to this exemption, extemporaneously dispensed medicines are not subject to evaluation by the TGA. Professional practice is governed by pharmacy boards in each state or territory. Although there have been few confirmed incidents of harm from compounded products in Australia, the potential is great in the absence of enforceable quality control measures. There have been reports of serious adverse events in the USA, mostly associated with improper compounding of sterile parenteral products.⁷ In the USA, compounding is also

Reasons for compounding medicines

Different dosage form required, for example liquid form required but only tablets available, ointment required instead of cream

Sensitivity/allergy to excipients and preservatives

Discontinued or unavailable medicine

Different dose or concentration required

Different route of administration required

Compliance problems, for example palatability

regulated by state pharmacy boards, however the federal Food and Drug Administration has taken action against companies that have embarked on large scale manufacture and supply of unapproved drugs under the guise of compounding.

A particular concern of the TGA is batch production (compounding a medicine for more than one patient). Until recently this was mostly undertaken by hospital pharmacies, but now has increased in other areas.

Traditionally, compounded medicines were simple dosage forms, but now some pharmacies are compounding complex dosage forms. Controlled-release formulations are an example that has already caused concern as variations in pharmaceutical performance such as dose dumping are possible. There are usually no or inadequate studies available on bioavailability and hence the compounder has to be aware of their ability and the prescriber has to balance potential harm against clinical need. A triad of informed patient, prescriber and compounder is essential.

Pharmacists are required to provide patient counselling on the appropriate use of compounded medicines. There is no consumer medicine information available for these products, so prescribers and pharmacists must ensure that the patient is aware of this and advise on the correct use, storage, expiry date and possible adverse effects and interactions. This counselling, information and education has to be communicated to each patient.

The way forward

The Pharmaceutical Society of Australia has developed Professional Practice Standards for compounding¹ as well as a specific compounding chapter in the Australian Pharmaceutical Formulary and Handbook. The TGA is currently working with pharmacy professional bodies and health departments to review and improve compounding standards in Australia.

Application and enforcement of practice standards has been inconsistent and under-resourced. A uniform approach to the current regulations and standards would potentially help to address some of the concerns about compounding.⁸ The demand for extemporaneously prepared products in pharmacies

is low, so the maintenance of compounding skills, equipment, formularies and standard procedures can be difficult and costly. This is leading to the development of specialised compounding practices.

Pharmacy compounding is an important and growing area of professional practice and potentially has a role in the effective treatment of patients with specific needs. Uniform compliance with the standards and regulations is therefore needed. Planning is under way for the development of more comprehensive compounding practice standards which will be critical to ensuring that only the highest quality products are prepared. All compounding activity (not just by pharmacists) should be undertaken to these high standards. Enforcement of these standards should also be uniform to ensure patient health and safety.

References

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Mr Feldschuh is a shareholder of Professional Compounding Centres of Australia (PCCA) and is a member of PCCA. His current position is Vice President, Pharmaceutical Society of Australia (PSA), Victorian branch. He is the PSA representative on the Pharmacy Manufacturing Technical Expert Reference Group, Therapeutic Goods Administration. He has previously owned two pharmacies.