TGA Consultation

Options for reform of the regulatory framework

for pharmacy compounding.

Regulatory impacts on Naturopaths

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Introduction

In June 2013 the TGA released the consultation document *Options for reform of the regulatory framework for pharmacy compounding* ('the consultation document'). It is important that the TGA addresses concerns regarding the current regulatory framework for the manufacture of extemporaneous preparations **in pharmacies** and that adequate assurance is in place that medicines manufactured in this way will meet acceptable standards of quality and safety. Importantly, despite significant consultation, the regulatory impact on naturopaths who do use extemporaneous compounding has not been previously identified. This may in part be due to the lack of direct consultation of key stakeholders in the naturopathy profession. The Australian Naturopathic Practitioners Association (ANPA) is seeking more ability to offering input to the TGA in matters that affect the medicines our practitioners use regularly. There is a legislative overlap between pharmacy, herbal and nutritional extemporaneous compounding. This highlights the risk of significant regulatory impact on naturopaths if due diligence to the consequences of the regulatory reform is not taken into account for the profession of naturopathy. The ANPA is pleased to offer recommendations supporting and preventing any unnecessary regulatory impact on naturopaths.

Background

Naturopathy

A naturopath is "a practitioner having core training in naturopathic principles and philosophy, as well as at least three of four practice modalities: (i) herbal medicine; (ii) nutritional medicine: and (iii) either massage or homeopathy".[1] As such, extemporaneous compounding of herbal nutritional or homeopathic medicine is core activity of naturopaths.

The ANPA

The ANPA was founded in 1975 and is a national association representing naturopaths. All members must have a minimum of an Advanced Diploma of Naturopathy, although many have much higher qualifications. Our members abide by a strict code of ethics as well as other association policies that guide clinical practice.

The ANPA represents naturopaths in the following ways:

- Advocacy to government at State and Federal levels.
- Support statutory registration for naturopaths.
- Panel member to the government on the Review of Private Health Insurance Rebates for Natural Therapies.

[1] Lin, V, Bensoussan, A, Myers, S.P, McCabe, P, Cohen, M, Hill, S, Howse, G 2005, *The Practice and Regulatory Requirements of Naturopathy and Western Herbal Medicine*, School of Public Health, La Trobe University, Victoria.

- Advocacy to private health insurers.
- Participation in the review of the Health Training Package (VET Sector).
- Foundation member and continued support for the Australian Register of Naturopaths and Herbalists (ARONAH).
- Significant focus on support for students and new graduates as they enter the profession.
- Ongoing educational and professionalization support for naturopaths.
- Collaboration with other health professionals creating bridges of understanding to improve health outcomes for the public.
- Communication with education providers across Australia and overseas offering naturopathy training.
- Regular contributions to the media raising the profile of naturopathy and awareness for the profession amongst other health professionals, the public and the media.

Extemporaneous compounding by Naturopaths

Due to the individualised philosophy of naturopaths they prescribe individual herbal formulations for their patients. In practice, this means that the majority of naturopathy consultations result in the extemporaneous compounding of a prescription. Naturopaths using herbal medicines predominately prescribe fluid extracts (which use a mixture of water and ethanol as the solvent, extracting using a process of maceration or cold percolation). The second most common prescription by naturopaths who use herbal medicine are herbal teas – that is combinations of dried herb material to be used by the patient to make tea. In the case of herbal teas, the mixing of different herb material for therapeutic purposes constitutes extemporaneous compounding. While herbal medicines are most commonly prescribed for internal use, a small percentage of herbal prescriptions by herbalists are for other traditional forms of herbal application, including extemporaneously compounded creams and poultices.

Naturopaths are limited in their prescriptions by the Poisons Standard 2012; unlike pharmacists they cannot extemporaneously compound or dispense any substance included in Schedule 2, 3, or 4 of this Standard. What this means is that medicines prescribed by naturopaths are of a low risk nature.

Relevant Legislation

At the time of the development of the Therapeutic Goods Act 1989 ('the Act'), the traditional practice of naturopaths in prescribing to their patients individualised herbal formulae of a low risk nature was recognised. As such, herbalists and naturopaths were included in Item 4 of Schedule 8 of the Therapeutic Goods Regulations 1990, *allowing them to continue their traditional practice without requiring a manufacturing license issued by the TGA.* (see Table 1 for the relevant extract.)

Table 1: Extract from Schedule 8 of the Therapeutic Goods Regulations 1990 – Persons exempt from the operation of Part 3-3 of the Act

Column 1 – Item	Column 2 – Persons	Column 3 – Matter in relation to which person is exempted
4	herbalists, nutritionists, naturopaths, practitioners of traditional Chinese medicine, or homeopathic practitioners engaged in the manufacture of any herbal, homeopathic or nutritional supplement preparation	where the preparation is for the use in the course of his or her business and: (a) The preparations are manufactured on premises that the person carrying on the business occupies and that he or she is able to close so as to exclude the public; and (b) the person carrying on the business: (i) supplies the preparation for administration to a particular person after consulting with that person; and (ii) uses his or her own judgement as to the treatment required

In order for the Schedule 8 exemption to operate, medicines manufactured by herbalists and naturopaths must also be exempt from the requirement to be entered into the Australian Register of Therapeutic Goods (the 'ARTG'). If they were required to be entered into the ARTG (as Listed medicines), they would also be required to be manufactured by a person who has a manufacturing license, in accordance with Section 26A(2)(e) of the Act:

"Section 26A(2) of the Act provides that the applicant must certify that:

> (e) if the medicine has been manufactured in Australia – each step in the manufacture of the medicine has been carried out by a person who is a holder of a license to carry out that step".

Since 1990, the herbal medicines manufactured, extemporaneously compounded and dispensed by herbalists and naturopaths have been exempt from the requirement to be entered in the ARTG through Schedule 5 of the Regulations. The relevant extract from Schedule 5 is highlighted in Table 2 below.

Table 2: Extract from Schedule 5 of the Therapeutic Goods Regulations 1990 – Therapeutic goods exempt from the operation of Parts 3-2 and 3-2A of the Act

Column 1 – Item	Column 2 – Therapeutic Goods
6	medicines (other than medicines used for gene therapy) that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person

As there is no separate entry for extemporaneously compounded herbal medicines in Schedule 5, it is clear that Item 6 of Schedule 5 of the Regulations applies to extemporaneous compounding and dispensing of medicines by herbalists and naturopaths as well as pharmacists. Thus, any changes to Item 6 of Schedule 5 of the Regulations will impact on the core activities of herbalists and naturopaths.

Responses

Option A – status quo

Maintaining the status quo through continued reliance on professional practice standards, existing regulations under the Act, and state and territory pharmacy inspection arrangements would have no foreseeable regulatory impact on naturopaths.

Option B – enhance co-regulation and update legislation

Any amendments to Item 2 of Schedule 8 of the Regulations would not have a regulatory impact on naturopaths. This is because herbalists and naturopaths are entered into a separate item in this Schedule, namely Item 4. However, any changes to Item 6 of Schedule 5 of the Regulations will impact on the practice of naturopaths.

Potential impacts are as follows:

(i) "require compounded medicines to be identified as such on their labels. This could be via a condition on exemption (amendments for Schedule 5A of the Therapeutic Goods Regulation 1990) or a requirement to comply with a standard (new Therapeutic Goods Order).

Regulatory impact: The proposal to require compounded medicines to be identified as such is aimed at addressing problems raised by the behaviour of some pharmacies, and is not relevant to the practice of herbalists who, as noted earlier, dispense low risk medicines compared with medicines or substances not included in S2, S3 or S4 of the Poisons Standard.

It is also unnecessary as herbal medicines are compounded after consultation with a patient by the herbalist. The patient is already well-aware that the medicine has been

compounded. The suggested wording the label requirement "Compounded medicine. Discuss with your pharmacist" would be inappropriate for herbal medicines and confusing to patients.

The suggestion of a requirement to comply with a new Therapeutic Goods Order is of concern. There is a risk that such an Order may be worded in a way that it applies to pharmacists only. If this was to occur, *there is a risk that the Order would nullify the application of Item 6, Schedule 5 to medicines dispensed and compounded by herbalists and naturopaths.*

(ii) Exempt compounded medicines from inclusion in the ARTG only when there is no suitable and available medicine on the ARTG, via amendments to Schedule 5A of the Therapeutic Goods Regulation 1990.

Regulatory impact:

- Who would be a credible judge of whether there is a suitable and available medicine?
- How would this be carried out? On a case by case basis?

This suggestion implies increased monitoring and auditing, both being time and cost intensive processes. Presumably, under the 100% cost recovery regulatory model for medicines the cost of this regulatory burden would be directly passed onto the group being regulated. This regulatory impact may put some compounding pharmacists out of business. A similar effect for naturopaths may result in financial hardship and they may be put out of business if these restrictions were enforced.

The practice of naturopaths using herbal medicine allows for tailoring bespoke preparations utilising a broad range of herbal materials – fluid extracts, teas, and topical preparations. These materials are compounded for the individual requirement of the patients.

This option would undermine the inclusion of aturopaths in Item 4 of Schedule 8 of the Regulations – that is to allow naturopaths to continue their traditional practice of prescribing to their patients individualised herbal formulae of a low risk nature.

(iii) Allow the Secretary to request information about exempt compounded medicines, via amendments to Schedule 5A of the Therapeutic Goods Regulation 1990.

Regulatory impact: The proposal to allow the Secretary to request information about compounded medicines, including active ingredient, formulation, shelf life, sterilisation process and labelling would result in significant, unnecessary regulatory burden for naturopaths. Naturopaths include information about medicines dispensed to each patient in patient records as a matter of course.

This proposal would result in naturopaths needing to keep an additional record to store this information separately. This would result in increased unnecessary administrative requirements and doubling up of record keeping resulting in time away from other clinic duties, increased bookkeeping expenses as well as potential increased staffing costs to meet these needs. Operating costs would increase and create financial hardship for many practitioners.

Option C – manufacturing licence for specified manufacture in pharmacies

These amendments would be made to Item(s) 2 and/or 3, and not Item 4, there would be no foreseeable regulatory impact on herbalists and naturopaths.

Recommendations

Recommendation 1

That, to differentiate medicines dispensed or extemporaneously compounded by herbalists and naturopaths from medicines dispensed or extemporaneously compounded by pharmacists, herbal medicines be entered as a separate Item in Schedule 5 of the Therapeutic Goods Regulation 1990. Appropriate wording for such an Item may be "herbal medicines that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person".

Recommendation 2

That, if herbal medicines are not entered as a separate Item in Schedule 5 (as per Recommendation 1 above), the TGA enacts any regulatory changes aimed at addressing the manufacture of extemporaneous preparations in pharmacies via Item(s) 2 and/or 3 of Schedule 8 of the Therapeutic Goods Regulation 1990.

Recommendation 3

That the TGA consult with the ANPA regarding any proposed amendments to Item 6 of Schedule 5 of the Therapeutic Goods Regulation 1990.