

Submission to the TGA consultation regulation impact statement 'Options for reform of the regulatory framework for pharmacy compounding':

Regulatory impact on herbalists and 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'). As stated in the consultation document "the purpose of this paper is to assist Australian Government decision making on how to address concerns that the current regulatory framework for the manufacture of extemporaneous preparations **in pharmacies** ('extemporaneously compounded medicines') does not provide adequate assurance that the medicines manufactured in this way will meet acceptable standards of quality and safety". The release of the consultation document follows a series of reviews and consultations on pharmacy extemporaneous compounding, and direct consultation with key stakeholders in the pharmacy and medicine manufacturing fields. It appears that despite significant consultation, the regulatory impact on herbalists and naturopaths has not been previously identified. This may in part be due to the lack of direct consultation of key stakeholders in the herbal medicine field. In this submission I seek to outline the legislative overlap between pharmacy and herbal extemporaneous compounding; highlight the risk of significant regulatory impact on herbalists and naturopaths if due care is not taken in the development of regulatory reform; and present my recommendations to the TGA of the best course of action to prevent unnecessary regulatory impact on naturopaths and herbalists.

Background

Herbalists and Naturopaths

A herbalist, or 'Western Herbal Medicine practitioner', is defined as "a health practitioner who engages in extemporaneous compounding of herbs for therapeutic uses for individuals under his or her care", while a naturopath is "a practitioner having core training in naturopathic principles and philosophy, and in 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 medicines is the primary activity of herbalists, and is a core activity of naturopaths.

Western herbal medicine, as practiced in Australia, is a traditional medicine based on European herbal medicine traditions.² Herbal medicine has a holistic philosophy, and the central aspect of the practice of herbal medicine is a focus on the individual rather than the disease, resulting in individualised herbal prescriptions.³

The practice of Western herbal medicines came to Australia with European settlement. While a detailed history of herbal medicine in Australia is not available, we do know that

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.

² National Herbalists Association of Australia 2013, National Herbalists Association of Australia, Concord West, NSW, viewed 11 July 2013.

³ Casey, M.G, Adams, J, Sibbritt, D 2007, 'An examination of the prescription and dispensing of medicines by Western herbal therapists: A national survey in Australia', *Complementary Therapies in Medicine*, vol.15, pp13-20.

there were a number of professional herbalist associations operating in a number of states in Australia during the early years of European settlement. In 1920, two NSW-based associations incorporated to form what is now called the National Herbalists Association of Australia (the 'NHAA'), with the Queensland Association of Herbalists and the South Australian Herbal Association becoming incorporated into the NHAA in 1952⁴.

Census data on naturopaths shows that the majority of naturopaths work part-time and are self-employed (60% and 72%, respectively)⁵. That is, naturopaths work part-time in small business. It is likely that herbalists would be similar to naturopaths in terms of employment status.

Extemporaneous compounding by Herbalists and Naturopaths

Due to the individualised philosophy of herbal medicine, the majority of herbalists and naturopaths prescribe individual herbal formulations for their patients. In practice, this means the majority of herbal medicine and naturopathic consultations result in the extemporaneous compounding of an herbal prescription. A recent survey of the prescribing habits of herbalists in Australia found that 96.3% of herbalists predominately prescribe individualised (and thus extemporaneously compounded) herbal medicines in their practice.⁶

Herbalists 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 herbalists is 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.^{7 8}

Herbalists and 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. In consequence, the herbal medicines prescribed by herbalists and naturopaths are of a low risk nature. Many herbal medicines of European tradition are also commonly used as foods in Australia. Examples include

⁴ National Herbalists Association of Australia 2013, National Herbalists Association of Australia, Concord West, NSW, viewed 11 July 2013.

⁵ Australian Bureau of Statistics 2009, *Complementary Therapies*, 4102.0 Australian Social Trends 2008, Australian Bureau of Statistics, viewed 13 July 2013.
<http://www.abs.gov.au/AUSSTATS/abs@nsf/Lookup/4102.0Chapter5202008>

⁶ Casey, M.G, Adams, J, Sibbritt, D 2007, 'An examination of the prescription and dispensing of medicines by Western herbal therapists: A national survey in Australia', *Complementary Therapies in Medicine*, vol.15, pp13-20.

⁷ Adams, J, Tan, E 1999, *Herbal manufacturing*, North Melbourne Institute of TAFE Printers, Preston, Victoria.

⁸ Casey, M.G, Adams, J, Sibbritt, D 2007, 'An examination of the prescription and dispensing of medicines by Western herbal therapists: A national survey in Australia', *Complementary Therapies in Medicine*, vol.15, pp13-20.

Chamomile, Peppermint, Garlic, Sage, Thyme, Liquorice, Sarsaparilla, Rosemary, Hops, Ginger, Fennel, Celery, Fenugreek, Elder flower, Cardamom, Turmeric, and Oats⁹.

Relevant Legislation

At the time of the development of the Therapeutic Goods Act 1989 ('the Act'), the traditional practice of herbalists and 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. Please see Table 1 below 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	<p>where the preparation is for the use in the course of his or her business and:</p> <ul style="list-style-type: none"> (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: <ul style="list-style-type: none"> (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

⁹ Mills, S 1989 *The Complete Guide to Modern Herbalism*, Thorsons, London.

However, in order for the Schedule 8 exemption to operate, the 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’). This is because 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 given 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.

Response to Options

Option A – status quo

I note that Option A – 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 herbalists and naturopaths.

Option B – enhance co-regulation and update legislation

Of the proposed legislative amendments, any amendments to Item 2 of Schedule 8 of the Regulations would not have a regulatory impact on herbalists and 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 herbalist and naturopaths. Potential impacts are detailed below.

- (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: As the proposal to require compounded medicines to be identified as such is aimed at addressing problems raised by the behaviour of some pharmacies, to require herbalists and naturopaths to also include this label information will result in an unnecessary increase in paperwork and regulatory burden. It is also unnecessary as herbal medicines are compounded after consultation with a patient: 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. More concerning, however, is the suggestion of a requirement to comply with a new Therapeutic Goods Order. 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: Herbal medicines prescribed by herbalists and naturopaths are individualised formula, compounded after in-depth consultation with a patient. Usually, this compounding is done immediately after consultation and therefore the patient leaves the consultation with their medicine. Most herbalists have as part of their clinic their own herbal dispensary¹⁰. A typical herbal dispensary might contain between 10 and 100 fluid extracts and 5 to 20 different dried herbs to form the basis of extemporaneous

¹⁰ Casey, M.G, Adams, J, Sibbritt, D 2007, ‘An examination of the prescription and dispensing of medicines by Western herbal therapists: A national survey in Australia’, *Complementary Therapies in Medicine*, vol.15, pp13-20.

compounding of herbal medicines. Yet there are many thousands of herbal medicines included in the ARTG, therefore if compounded medicines were only exempt from inclusion in the ARTG when there was suitable and available medicine in the ARTG, in order for the herbalist/naturopath to provide the same service to their patients (ie. to provide individualised herbal medicine immediately after consultation), the herbalist/naturopath would have to have in their dispensary every herbal medicine Listed on the ARTG! This would be both impractical and financially unachievable. Further, it would limit the ability of the herbalist/naturopath to utilise their judgment as to the most appropriate source or brand of herbal product to prescribe in any given situation. As such, it would undermine the intention of including herbalists and naturopaths in Item 4 of Schedule 8 of the Regulations – that is to allow herbalists/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 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 and herbalists. While herbalists and naturopaths include information about medicines dispensed to each patient in patient records as a matter of course, this proposal would result in herbalists/naturopaths needing to also record and store this information separately. This would result in increased paperwork and time away from other clinic duties, and increased bookkeeping expenses.

Option C – manufacturing licence for specified manufacture in pharmacies

I note that the option to require a place where a pharmacist manufactures to hold a licence as a manufacturing site in a wider range of circumstances proposes to effect these changes through amendments to Schedule 8 of the Therapeutic Goods Regulation 1990. Given that these amendments would be made to Item(s) 2 and/or 3, and not made to 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 engage naturopathic and herbal professional associations, including the National Herbalists Association of Australia, in direct consultation regarding any proposed amendments to Item 6 of Schedule 5 of the Therapeutic Goods Regulation 1990.