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Commonwealth Department of Health and Aged Care

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Helen

Dear ~~Mrs~~ Owens

ADDITIONAL SUBMISSION TO PRODUCTIVITY COMMISSION REGARDING THE REGULATION OF COMPLEMENTARY MEDICINES

Further to the Therapeutic Goods Administration's (TGA) previous submission of 7 December 2000, please find attached an additional submission regarding the regulation of complementary medicines. This additional submission details the unique approach taken by TGA to the regulation of complementary medicines. This approach is commensurate with the risks and benefits associated with this category of medicines and is clearly distinguished from the approach taken to the regulation of prescription medicines and medical devices described in the previous submission.

I trust this information will assist you further with your inquiry.

Yours sincerely,

Regards
Terry

Terry Slater
National Manager
30 January 2001

REGULATION OF COMPLEMENTARY MEDICINES

Additional submission by the Therapeutic Goods Administration to the Productivity Commission Review of Cost Recovery by Commonwealth Agencies
January 2001

Australia has a unique regulatory system for complementary medicines that enables streamlined, reduced cost access to the market for complementary healthcare products, while delivering sufficient post-market controls to ensure consumers can be confident in the complementary medicines they choose to use.

Complementary medicines regulatory system

Complementary medicines include herbal medicines, vitamins, minerals, nutritional supplements, aromatherapy oils and certain homoeopathic medicines. Complementary medicines are not foods. Although they may contain food-derived ingredients, typically they contain concentrated material and are used for different reasons and in a different manner, to foods.

Complementary medicines are part of the medicines continuum and are regulated under therapeutics goods legislation (the *Therapeutic Goods Act 1989* ('the Act') and the related Regulations and Orders). The overall objective of this legislation is to ensure the quality, safety and efficacy of therapeutic goods available to the Australian public. Within the TGA, the Office of Complementary Medicines has responsibility for overseeing the regulation of complementary medicines.

To deliver this objective, management of risks associated with therapeutic goods, including complementary medicines, is exerted through three main processes:

- licensing of manufacturers;
- pre-market assessment of products; and
- post-market regulatory activity.

Licensing of manufacturers
Manufacturers of therapeutic goods must be licensed or otherwise approved and their manufacturing processes must comply with the principles of Good Manufacturing Practice (GMP). GMP licensing is a major factor in ensuring that therapeutic goods supplied in Australia are safe and high quality, and contributes to the international standing of the Australian industry.

Pre-market assessment
Complementary medicines are generally at the lower risk end of the medicines continuum and, in recognition of this, the majority go through a streamlined, less expensive, market entry process known as listing. These lower-risk products are individually assessed, but not evaluated, by the TGA before they are released onto the market. In determining the

level of risk for these products, a number of factors are taken into account, including the strength of the product, side effects, potential harm through prolonged use, toxicity and the seriousness of the medical condition for which the product is to be used.

The substances or ingredients from which low risk products are formulated must undergo pre-market evaluation for safety and quality. Products may only be supplied providing they contain substances that have been evaluated and approved by the TGA. Once approved for supply, these products are included on the Australian Register of Therapeutic Goods as "Listed" products and carry an identifying "AUST L" number.

The safety of potential Listable substances which may be used in complementary medicines is established through an evaluation process undertaken by the Office of Complementary Medicines within the TGA. Based on the information and data available, a comprehensive evaluation report on the safety of the substance is prepared by TGA staff. The information and data is normally supplied by an applicant who is requesting evaluation of the substance. The evaluation report is put forward for consideration by the Complementary Medicines Evaluation Committee (CMEC), a statutory expert committee. CMEC makes recommendations to the TGA regarding how the substance should be regulated, and the TGA makes a regulatory decision based on those recommendations and any other relevant factors. Such substances are then added to the list of substances available for use in listed complementary medicines.

Listed medicines can carry low level labeling claims and indications (e.g for nutritional support or the relief of symptoms) which are not evaluated by the TGA before market entry. The Act requires that sponsors hold appropriate evidence to support claims made at the time of Listing, and this is enforced through post-market audit and other surveillance activities. Only where the sponsors of complementary medicines seek to make higher level therapeutic claims about their products (for example, for the treatment of iron deficiency anaemia), or where they contain higher risk substances, are the products required to undergo Registration, that is, individual pre-market evaluation for safety, quality *and* efficacy. The requirement to hold evidence to support claims made about a medicine is a reasonable one and allows Australian consumers to have confidence in the value of the complementary medicines they purchase.

This streamlined approach to assessment for low risk products addresses the need to improve market access to quality new complementary medicines while maintaining public health and safety. It allows for timely market access, but with a level of pre-market evaluation of the components of each medicine that delivers an assurance of safe, quality products. However, to ensure a high level of public health and safety, an important feature of this risk management approach is that the early market access for low risk complementary healthcare products is supported by appropriate post-market regulatory activity.

Post-market strategy

An important feature of a risk management approach to medicines regulation is an effective post-market surveillance system. The TGA's post-market surveillance system

for complementary medicines includes post-market (desk-based) review of products, monitoring and surveillance activities in the marketplace, problem reports and complaints, and laboratory testing to ensure compliance with the legislation. An adverse reaction reporting system for therapeutic goods is well-established and consideration is currently being given to extending its effectiveness to help ensure any problems arising from the use of complementary medicines are more readily identified.

It is certainly true that complementary medicines supplied in Australia have a history of low risk supply. But this history is not due entirely to the medicines being intrinsically safe. The regulatory system in place in Australia has worked to ensure that safety standards are met and that consumers can have confidence in the products they are buying. Further, low risk does not equate with no risk, and TGA's post-market surveillance program has effectively dealt with a number of safety problems that have arisen. For example, following reports of kidney disease and cancer overseas associated with the herb *Aristolochia*, the TGA recently investigated all products included in the Australian Register of Therapeutic Goods that contained herbs likely to be substituted, inadvertently, for the toxic *Aristolochia* species. This resulted in the identification of eight contaminated products which were subjected to urgent recall. Recent labelling changes for products containing the herbs guarana (*Paullinia cupana*) and St John's Wort (*Hypericum perforatum*) have been implemented in response to serious health concerns identified with their use.

The streamlined, co-regulatory approval processes that apply to complementary medicines, and the reduced fees and charges sponsors pay, has, in essence, already created a separate regulatory category for these products. Indeed, the Australian system of regulating complementary medicines is providing a model for other countries as they grapple to deal with this class of medicines.

Costs associated with the regulation of complementary medicines

The fees paid to list new complementary medicines are far lower than those for over-the-counter pharmaceutical products and for prescription medicines. The reduced fees reflect the low risk nature of these products. Additional fees and charges for listed medicines were negotiated and agreed with the complementary medicines industry in January 2000. The new fee schedules are still below what they would have been if TGA had simply doubled the fees and charges from the 50% rate following the Government's decision to move from 50% to 100% cost recovery.

The relevant product-related fees and charges compared to the 50% target on 30 June 1996 are given in the table below. These represent a 4.5% discount and 31.2% discount on what would have been required for application fees and annual charges respectively. Variation processing fees have been held at the level charged under the 50% cost recovery system and in fact some variations are no longer subject to fees and charges at all.

	50% Cost Recovery 1/7/96 $	Projected 100% Cost Recovery $	100% Cost Recovery CPI adjusted $	Actual Fee 2000/1 At 1.7.00 $	Actual Fee Increase $	Discount %
Annual Charge	200	400	418	350	150	31.2
Application Fee	200	400	418	400	200	4.5
Processing Fee for Variation	200	400	418	200	nil	47

The TGA also charges fees for the evaluation of new listable complementary medicine substances. These fees start from a base of $4,300 and increase depending on the number of pages of clinical and toxicological data submitted, thus reflecting the cost of evaluating the submitted material. These charges are significantly lower than those charged for the evaluation of a new chemical entity for use in a prescription medicine and, again, this reflects the low risk nature of these substances.

Fees and charges cover not only the direct cost to the TGA of listing a complementary medicine. Other very important areas supported by these fees are:

- Post-market surveillance to remove dangerous (e.g. those contaminated with *Aristolochia*) and sub-standard products from the market. This system builds consumer confidence in Australian products.

- Enhancement of the adverse drug reactions database, to increase reporting of adverse reactions in for complementary medicines, a sector where there has traditionally been a low level of reporting. Information from this database is important not only to alert government and industry to emerging problems associated with medicine usage, but also provides data that can be used to demonstrate the low risk nature of complementary medicines.

- Refinement of the ELF system to further streamline approval processes.

- Development of guidelines to assist sponsors (e.g. guidelines defining the composition and purity of complementary medicine substances).

- Assistance to members of the public on issues relating to complementary medicines.

- Liaison with other governments (internationally and within Australia), which helps to facilitate trade in complementary medicines.

While some of these outcomes do indeed have a "public interest" component, they arise directly from the supply of complementary medicines in Australia. These activities would not be necessary if the complementary medicines sector did not exist.

What are some of the recent deliverables from this regulatory approach?

The levels of evidence Guidelines
These Guidelines were developed to assist sponsors to assess the types of claims they can make for their listed medicine, and to identify the evidence base they need to underpin these claims. The Guidelines support the new principles-based Therapeutic Goods Advertising Code, launched in April 2000, which has allowed a wider range of claims for complementary medicines, including claims based on traditional evidence.

The Listing system
The Listing system which regulates low risk products (AUSTL products) is built around an Electronic Lodgement Facility (ELF) which allows sponsors to lodge their applications to List new products electronically. Applications are submitted and checked for compliance with the legislation by the TGA, after which approval to supply the product is given. Most applications are turned around within about 10 days, except where serious regulatory problems are identified, giving streamlined market access for these products. Before the ELF system was introduced, turnaround time of applications was of the order of 70 days.

In 2001 a new version of the ELF system will be launched which will allow even more rapid turnaround for applications, such that the majority of them could be processed with almost immediate turnaround. This speedier market access will be facilitated by a "smart" computer system which will validate information provided in applications against the relevant legislation as the application is lodged. It will also be built on programming that will minimise data entry requirements.

Approval of new complementary medicine substances
Prior to 1998, there was little scope for the approval of new complementary medicine substances for use in listed medicines. With the establishment of the first Complementary Medicines Evaluation Committee (CMEC) in late 1997, a process was developed for reviewing such substances outside the necessarily rigorous system used for new chemical entities in prescription medicines. In less than 3 years of operation, CMEC has recommended the approval of 54 new substances for use in Listable medicines (which equates to 119 new individual substances when the different forms or salts of new substances are taken into account). More than 1100 new complementary medicines have been approved for Listing containing one or more of these new substances.

Conclusion

The regulatory system for complementary medicines must continue to ensure that Australians who choose to use complementary medicines can do so with the highest possible level of confidence in their overall safety and quality. Recent reforms to the regulation of complementary medicines in Australia build on the existing regulatory system to provide a sound risk-based management system to:

- ensure a level of regulation commensurate with the low risk nature of most complementary medicines;
- meet the need to improve market access to quality new products while maintaining public health and safety;
- set the test for substantiation of therapeutic claims;
- enhance post-market monitoring of complementary medicines;
- enable involvement of the complementary medicines industry in providing expert advice to government on regulatory policies for complementary medicines.

The current system of regulation of complementary medicines allows consumers to have faith in the quality, safety and efficacy of complementary medicines. Without faith in the products available to them, consumers are unlikely to continue to support the Australian industry at the levels they now do.