Wednesday 27th September 2000

Cost Recovery Inquiry
Productivity Commission
Locked Bag 2,
Collins Street East
Melbourne
VICTORIA 8003

Baulkham Hills 3.45pm

Good afternoon,

RE: SUBMISSION TO COST RECOVERY INQUIRY

Nature's Sunshine Products of Australia Pty Ltd (NSP) market a range of 200 plus complementary healthcare products throughout Australia to health food stores, practitioners and independent distributors. NSP are Australian owned and operated, and have been operating since February 1981.

NSP is part of a globally operating direct sales marketing company specialising in complementary healthcare products in some forty countries world wide.

NSP are active members of the Direct Selling Association of Australia Inc, (DSAA) the National Herbalists Association of Australia (NHAA) and the Complimentary Healthcare Council of Australia.(CHC)

We are opposed to the Australian Commonwealth's Government requirement for 100% cost recovery on the basis of it being unjustified, inefficient and not required or needed by the Complimentary Healthcare industry. In contrast to many direct sales or multi level marketing competitors, NSP Australia strives to comply with all applicable legislation. The cost of regulatory compliance in Australia is disproportionately high for NSP Australia, within the company group, given that in most other markets in which the company operates the products are treated as dietary supplements. But even in other countries with registration requirements the cost is not a great as in Australia.

This cost would be bearable if NSP Australia felt they were getting value for money. Sadly we don't feel we are doing so.

NSP market herbs and vitamins. The average recommended retail price is around $ 22.78.
In Australia herbal products which are for use in, or in connection with, preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals, or influencing, inhibiting or modifying a physiological process in persons or animals, are considered to be medicines.

Medicines must be recorded on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied (which includes import, export, sale, and advertising). This is a pre-clearance process which has been in operation since 1991. Herbal medicines may be either Listed or Registered. Most are Listed.

In order to be Listed on the ARTG an electronic listing form (ELF) utilising software designed by the Australian Therapeutic Goods Administration (TGA) must be completed by the applicant or applicant's agent. This self-validating form process ensures that the manufacture of the product, including packing , are complying with drug level Good Manufacturing Practice (GMP) and that the ingredients in the product are eligible for use in Australia at the concentration or strength proposed. Sponsors of Listed medicines are required to posses suitable evidence of efficacy at the time of application and for the duration of the product's life.

The Listing application form, one for each product, records the quantified formula, indications / claims, physical characteristics, storage conditions and shelf-life, and commits the applicant / sponsor to specific pharmacopoeial type requirements including label copy. Through the Listing process the sponsor also commits to mandatory flag or warning statements on the label according to the ingredients of the product or the claims made.

Each product, if Listed costs $ 400.00 application fee and an annual fee of $ 350.00, that's a first year listing fee of $ 750.00. Any variation to this product incurs a fee of $ 200.00. There is provision in the second and subsequent years for exemption status from the annual fee if the product is of "low volume, low value." (ie the charge for listing is greater than 6% of the wholesale turnover of the goods.)

A Registered product costs $ 650.00 application fee, an evaluation fee of up to $ 30,000.00 and an annual fee of $ 465.00.

On top of these fees a certificate of Good Manufacturing Practice (GMP) must be produced at the time of the application to ensure that the product is manufactured to GMP Standards. The GMP certificate for NSP costs $ 10,925.00. This amount includes an inspection fee of $ 6,705.00 for a 9 hour audit, the balance being air fares, accommodation and travel expenses.

Yes, we are required to fly a GMP auditor from Canberra to Utah, the United States of America for a nine hour inspection visit. This is required every 18 months. This is simply ludicrous.

Further, because of the complexity of the Registration or Listing process it is not viable for a small company of our size to do our own regulatory management. Our solution is to contract the services of a regulatory affairs consultant thereby incurring additional costs and fees.

Prior to the introduction of the Good and Services Tax , none of our herbal and vitamin products were effected by the Wholesale Sales Tax. Now the consumer pays 10% extra for our products.

Never before have there been so many assaults on our industry and business. There is Government Regulation, the Therapeutic Goods Act compliance costs, advertising guidelines and prohibitions, Good Manufacturing Practices (GMP) compliance costs and now the Goods and Services Tax, which I honestly believe for our industry is a tax upon a tax upon a tax upon a tax. A tax to apply to sell a product, a further tax to register a product for a year, a tax for GMP inspection and now a further 10% GST. This is ridiculous.

Our objection to 100% cost recovery by the Australian Commonwealth Government for the Complimentary Healthcare Industry is;

1/ There is too much restriction, prohibition and costs involved with low- risk, trouble free complementary health care products. Australians spend 621 million dollars a year on vitamins, minerals, herbal products, nutritional supplements, naturopathic and homoeopathic preparations.

2/ The safety and protection of the consumer is disproportionate with the associated costs of Registration or Listing and the present regulatory environment.

3/ The costs incurred by industry members to comply with and contribute 100% cost recovery are anti-competitive and deny consumers access to a full range of cost effective, low–risk health care supplements.

4/ With some 18,000 Listed products on the ARTG @ $350.00 per annum, how can any Government body justify 6.3 million dollars to keep a register and infrastructure. We accept that new applications should attract a fee. But even in the current process applicants do most of the work. We do not accept that past applications which are simply held on a computer record should attract a maintenance fee at the level that we are now paying.

Unless a part of that fee go toward supporting those signifying their compliance with the regulatory system by their ongoing financial contribution through more effectively controlling the non-compliers.

5/ Consumers of complementary health care products are saving the Australian Government money on future health related sickness and illness. Why “penalise” a consumer for actively taking an interest and managing their health care.
6/ Because products are manufactured overseas NSP has to pay additionally for inspection of the US manufacturing facility by the Australian inspectorate.

7/ The TGA is not noticeably controlling illegal operations that impact on the business in the direct marketing or direct selling environment. Non-compliant competitors have an advantage in their product costs, and the formulations offered.

9/ It seems that under cost-recovery we are only treading water.

10/ Much cost and effort is being put into a 'perfect computer-based recording system' to achieve what? Little more than is achieved now.

11/ With the introduction of GST this heavily regulated industry with high regulatory compliance costs is receiving no relief. In a sense it is paying twice. At least the TGA fees have been recognised as being tax exempt, but the requirement to pay GST and pay annual maintenance fees takes its toll.

Thank you for the opportunity to make this submission. I am happy to make myself available for any questions, clarification or public hearings.

Regards,

Stephen C. Webster
MANAGING DIRECTOR