AUSTRALIAN SELF-MEDICATION INDUSTRY

BETTER HEALTH THROUGH RESPONSIBLE SELF-CARE

Submission to the Regulation Taskforce

by

Australian Self-Medication Industry

Relating to the Scheduling of Drugs and Poisons

November 2005

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This submission

This submission is made by Australian Self-Medication Industry (ASMI). ASMI represents the makers of non-prescription medicines, including complementary medicines. Turnover of the industry is estimated at $A4bn.

The non-prescription medicines industry is regulated under the Therapeutic Goods Act. Part of that regulatory regime is the system for "Uniform" Scheduling of Drugs and Poisons.

The present scheme

The system is provided for in Part 6.3 of the Therapeutic Goods Act, reproduced at Attachment 1. This part establishes the National Drugs and Poisons Schedule Committee (NDPSC) and entrenches a right of veto in the State and Territory Members.

The whole scheme rests on an over-inflated regard for "States Rights". It is not uniform; it is not simple or straightforward; and it places a heavy and unnecessary burden of compliance on industry. These matters have been detailed many times to Government, most recently in the Submission referred to below.

Industry, though its predecessor the Proprietary Medicines Association of Australia and now through ASMI, has been trying for years to get the Australian Government to take responsibility and leadership for the scheduling scheme. For whatever reason — and we are never told — there has been a reluctance to reform the system. With the exception of sole traders — who are very small players in the manufacture and supply of therapeutic goods — all sectors of the industry could be covered by a truly uniform scheme.

A new opportunity now presents itself. With effect from 1 July 2006, the Australian and New Zealand Governments will create a joint agency to regulate therapeutic goods. Now, in addition to the corporations power under the Constitution, there is also available the external affairs power, so that a uniform system can "cover the field".

Industry was dismayed to learn recently that some sort of deal has been struck with the States so that the old, inefficient, costly system will be preserved. Industry was never consulted about the matter and our well-known views were disregarded.

The issues

For over ten years, since the Industry Commission examined the pharmaceutical industry, ASMI has maintained a consistent approach to this matter. Rather than repeat the story, we attach copies of two recent submissions which make the case for regulatory reform. These are:

- Submission to the House of Representatives Legal and Constitutional Affairs Committee (Attachment 2); and
- Submission to the Implementation Group for the Trans-Tasman Agency and related "Draft Scheduling Model". (Attachment 3).

This issue is a serious and vexatious one for this industry. For no good reason, our industry, which operates on the basis that Australia (and New Zealand) is one unified market, must submit to the whims of State particularism.

The body responsible for scheduling decisions (which relate to market access) also decides what products may be advertised. Its decisions fly in the face of economic reality. For example, a weight-loss product, recently scheduled down from Prescription-only to Pharmacist Only (S3) has repeatedly been denied permission to be advertised. There is no appeal process for such decisions other than judicial review. As well, any scheduling decision which requires to be given legislative effect is "ratified" by all eight jurisdictions in various, but each different, legislative regimes. The legislative programs of the jurisdictions are not aligned and there are always delays and uncertainties about when and where decisions actually take effect.

This is no way for Australian industry to operate in 2005. There is absolutely no warrant for it on grounds of public safety. It is just that the federal bureaucracy won't take on its colleagues in eight other jurisdictions — soon to be nine.

Conclusion

On grounds of efficiency, simplicity and equity, there is no justification for the present approach. **We urge this Taskforce to look with clear eyes at this situation and to recommend some commonsense and resolute action by the Australian Government to take over the responsibilities the Constitution gives it.**

Attachment 1

Attachment 2

Attachment 3