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Submission to the

Commonwealth Commission of Audit

by

Australian Self-Medication Industry

November 2013

This submission

ASMI is pleased to have an opportunity to present our industry's concerns to the Commission. This submission has to be brief but we would be happy to respond to any questions the Commission may raise.

Non-prescription medicines

ASMI represents the makers of non-prescription medicines in Australia.[1] These include the range of products people will find in their bathroom cabinets, and they will have bought them from a pharmacy or supermarket, or similar.

Our products are thus medicines which are "generally regarded as safe" and which regulators in Australia (and around the world) have decided do not need to be supplied on prescription.[2]

The crisis in healthcare …

Many observers of the condition of healthcare in Australia see a looming crisis, where demand is going to exceed supply. We are going to have to do better with fewer resources. We are going to have to find a better way to meet the challenges.

… and a way forward

ASMI and the Pharmacy Guild have worked together to propose a Self Care Alliance. Our proposal is at Attachment 1. **We recommend that the Commission examine this proposal carefully and propose that the Government explore the idea with the groups and professions listed on p. 11 of our Attachment 1**.

As a nation, we have to act before the present healthcare systems cease to be able to cope. As will appear below, we believe that **the ideas in our paper accord with the sentiments and principles set out in the Commission's TOR**.

Guiding principles for the Commission

The TOR ask the Commission to be guided by three principles:

> "government should have respect for taxpayers in the care with which it spends every dollar of revenue;

[1] These include so-called "over the counter" medications and complementary medicines as well. In regulatory terms, these groups include Listed products and some non-prescription Registered products. Registered products are assessed by the Therapeutic Goods Administration (TGA) for quality, safety and efficacy and Listed for the first two only.

[2] That is, without the intervention of a "learned intermediary" – usually the GP or other medical practitioner.

government should do for people what they cannot do, or cannot do efficiently, for themselves, but no more; and

government should live within its means."

Each of these principles resonates strongly with our members. They operate in an increasingly competitive global environment. The extents to which government helps – or hinders – their competitiveness are thus keenly felt. In this submission, we trust the Commission will readily perceive how important to ASMI these principles are.

In particular –

- the regulatory operations of the Therapeutic Goods Administration (TGA) – their efficiency, cost, and effectiveness – are vital to the therapeutic goods industry. The operations of the TGA are 100% cost recovered but industry has limited say about how those costs are arrived at.

- The regulatory design for therapeutic products at present tends toward command and control, as opposed to self regulation. This is especially notable in the areas of "scheduling" of medicines and of advertising controls, as set out below.

- It is a truth universally accepted that government should live within its means. Clearly, the more complex and intrusive the regulations are, the more it costs.[3] This submission identifies, in general terms, a few major issues capable of improvement.

"Blueprint for reform"

ASMI acknowledges that, over the last few years, the TGA has adopted a *Blueprint for reform*.[4] Some progress has been made. But the fundamental preference for command and control has to be replaced by approaches evident in world best regulatory practice, if real progress, consistent with the Commission's guidance principles, is to be achieved.

We have been at pains to indicate to the TGA, the Department and Ministers that ASMI is keen to cooperate in achieving real reform. We have cooperated with government in every possible way and intend to continue to do so.

Deciding what medicines are "safe"

Everyone in the medicines business understands that no medicine is 100% "safe", 100% of the time. There are risks that accompany the benefits. So lines have to be drawn.

The way to do this, ASMI believes, is by a **rational risk/benefit analysis**. As well, though, Australia – its consumers and regulators – do not need to reinvent the wheel. Indeed, in our view they should not.[5]

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[3] A classic case of unnecessary "gold plating" is to be found in the TGA's decision to change years of practice and individually approve even the most minor of changes to therapeutic products. ASMI considers – and told the TGA – that its views of s. 9D of the Therapeutic Goods Act was not soundly based. Information on the TGA's consultation is available at [http://www.tga.gov.au/newsroom/consult-pm-minor-variations-121210.htm]. The ASMI submission is available here [http://www.tga.gov.au/pdf/submissions/consult-pm-minor-variations-121210-submission-asmi.pdf]

[4] Information on the TGA's "blueprint is available at [www.tga.gov.au/about/tga-reforms-blueprint.htm]

[5] Except in rare cases where our circumstances differ from the industrialised countries with which we compare ourselves – e.g. the US, Canada, Europe and – increasingly – Asia. The most notable example is sun-screens, for obvious reasons.

It is the case, however, that, in our view, the rules imposed on industry in the name of the public's protection are generally more stringent than those of our overseas comparators. And, by the test of public benefit, often needlessly so.

The costs of regulation

It follows that Australia's failure to harmonise and rationalise our medicines regulation to meet world best practice standards to the greatest possible extent -

- is costing industry and the community money and resources which could be better deployed for community benefit;
- makes it hard for our industry to grow overseas markets, which our members desperately need to achieve economies of scale;
- engenders unacceptable delays in regulatory approval processes, again incurring unnecessary costs;
- sanctions the proliferation of red-tape for no discernibly acceptable public health outcomes[6]; and
- hinders the achievement of the objectives of ASMI's Self Care agenda.

Self-care

On the ASMI website[7], the Commission will find a detailed account of ASMI's views on self care and related initiatives. ASMI has been advocating for a greater emphasis on self care for some time now.

Fundamentally, this approach is based on our belief that the Australian consumer is neither a child nor an irresponsible idiot. Our research shows that the typical consumer who buys the medicine is "Dr Mum" and that she reads the label and chooses carefully.[8] We thus find much in the Commission's second guidance principle about what government should, or should not, do for people to agree with.

In many of the countries with which we compare ourselves, the regulators trust their consumers to choose and to self administer[9] their medications, up to the point where they seek professional treatment.

We request the Commission to find that the Self Care approach, combined with a better regulatory design, has the potential to advance the guiding principles in its TOR. And in the longer term and with a broader scope, that the Self Care Alliance must be advanced.

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[6] According to a very recent review of Director Sentiment for the Australian Institute of Company Directors, 33% of those surveyed saw "Too much regulatory red tape" and "Global economic uncertainty" as their top two concerns. In the case of our industry, the first of these compounds the difficulties of the second. (*The Australian,* 22 November 2013).

[7] www.asmi.com.au/self-care/self-care.aspx

[8] In our modern society, people rely on advertising, magazines and the Net for information. As consumers of medicines, people want and need information, oftener perhaps than the rare (and often brief) occasions they see a GP or pharmacist. (See also below ASMI's concerns at current regulation of therapeutic goods advertising).

[9] That is, without prescription but possibly using pharmacist advice, according to the medicine's classification.

Self care and its role in consumer health

Over recent years, a number of stakeholders in the consumer healthcare sector have discussed the concept of self care and the role it could play in an evolving and more sustainable healthcare system.

Self care entails individuals taking greater personal interest in, and responsibility for, their health and wellbeing through practices including lifestyle, appropriate use of medicines, diet and exercise.

Self care is aimed at empowering consumers through improved health literacy, and equipping them for the prevention and self-management of acute and chronic conditions. At its core is a shift from 'cure' to prevention, and a focus on activities and decisions that people make for themselves so that they maintain a good level of physical and mental health.

The World Health Organisation defines self care as "activities individuals, families and communities undertake with the intention of enhancing health, preventing disease, limiting illness and restoring health. These activities are derived from knowledge and skills from the pool of both professional and lay experience. They are undertaken by lay people on their own behalf either separately or in participative collaboration with professionals".

In its broadest sense, self care entails taking personal responsibility for health, wellbeing and appropriate use of all types of healthcare and services, including:

- Staying fit and healthy
- Recognising and reducing amenable risk factors
- Recognising quality medicines and using them appropriately
- Choosing quality healthcare providers
- Self-care of minor conditions
- Taking responsibility via active management of the care of chronic conditions.

It is accepted that self care will not suit everyone. Those facing economic and social disadvantage, for example, and those with complex health problems are unlikely to be in a position to benefit from wider self care.

But there are many individuals and families who are likely to embrace an opportunity to be more proactive in their healthcare, and adopt strategies that will give them a more productive and healthy life.

An important point to remember is that self care does not imply that individuals are left to look after themselves. Rather, the emphasis is on the partnership and the relationship between consumers and their healthcare professionals including GPs and pharmacists.

"Scheduling"

On top of the categorisation of OTC medicines as Listed or Registered, Australia has a system of "Scheduling" Drugs and Poisons. The Schedule is drawn up after consultation with all the States and they effectively have a veto on its contents. The Commission may not know, for example, that you can buy a small (e.g. 20 tablets) pack of paracetamol or ibuprofen anywhere but larger packs must be bought from a pharmacy.

It is important that Australia's scheduling arrangements

- are determined by applying standard risk/benefit analysis processes[10];
- are capable of harmonisation with New Zealand processes[11];
- are not used, as is now the case, to inhibit the advertising of some "Schedule 3" products[12]; and

[10] When the TG Act was being amended some years ago, ASMI asked that the scheduling of "poisons" follow risk/benefit processes. The Government of the day declined to amend the Bill to this effect.
[11] See below regarding ANZTPA.

- do not inhibit or prevent the growth of our export markets, especially to Asia.

ASMI submits that there is considerable room for improvement on all these fronts.

We note that, when the Scheduling system was imported into the Therapeutic Goods Act some years ago, a review was mandated to occur this year. ASMI has made a strong submission to the review.[13] We do not know the outcome although we have been given to understand that a report has gone to the Minister. **But we do ask the Commission to take a close interest in this matter, in the hope that the outcome of the statutory review will go some way to satisfy the four issues set out above.**

Advertising of therapeutic products

There exists a labyrinth of complex interlocking statutory, regulatory, co-regulatory and customary practice processes, all designed to *control* the advertising of therapeutic products. There have been efforts over quite some time to improve and simplify these arrangements and ASMI has been in the forefront of these efforts. The TGA put out a consultation paper earlier this year.[14] ASMI's comments reflected industry's dismay that the former Government seemed to want to revert to old-fashioned command and control arrangements, instead of refining and improving the co-regulatory models, which we believe have worked pretty well on them.[15]

We request the Commission to examine the arguments in our detailed submission. In brief, we believe present arrangements have been effective, although capable of improvement.

We especially believe, however, that Australia and New Zealand *must* harmonise their rules if the Joint Agency is to have any prospect of success, for reasons set out below.

We ask the Commission to find that the TGA proposals do not accord with the principles set out in its TOR and should be re-examined, especially to accord with NZ arrangements.

In particular, we ask the Commission to find that the present "rules" prohibiting the advertising of certain Schedule 3 substances are unnecessary, anti-competitive and do nothing for public health. To assist the Commission we have included a summary of the ASMI proposal as Attachment 2.

ANZTPA

It is in our and NZ's interest to move to the proposed joint therapeutic products agency. The last effort foundered some years ago, one result being that New Zealand is now developing a separate regulatory scheme for "natural health products". This is much to be regretted.

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[12] See below regarding the present controls on advertising of medicines.

[13] More information about the review is available at [http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-substances-review.htm]. A copy of the ASMI submission is available at [http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-substances-review-asmi-2013.htm]

[14] More information about the TGA's advertising consultation is available at [http://www.tga.gov.au/newsroom/consult-advertising-ris-130531.htm]

[15] The submissions to this consultation have not been published yet, but ASMI can provide the Commission with a copy of our submission if that would assist the Commission.

ASMI has made some general and preliminary comment on the development of the scheme this second time around.[16] In summary, we have told the Government:

" - ASMI welcomes the open minded approach "to shape the thinking around the design and operation of the scheme" as opposed to proceeding along a predetermined path.

- We agree generally with the principles applied.

- Without a finality of the overall design of the scheme our comments must be treated within the context they are given. As significant policy areas of the scheme not described in the paper become apparent and with the description subject to further change, so too may the positions and suggestions offered by us need to be amended.

- This is an opportunity to learn from and **adopt approaches which reflect the best regulatory practice from Australia, New Zealand and the rest of the world.**[17]

- Early communication of the overall ANZTPA project plan including active engagement and consultation on the plans for transition is critical to effectively minimising the burden of transition for industry.

We remain committed to work with Government, the TGA and Medsafe and other stakeholders in the development of a risk based regulatory scheme under ANZTPA consistent with international best practice that will achieve the stated objectives. We look forward to a consultation process that engages effectively with all stakeholders."

The Commission will note from our submission to the TGA that ASMI does not believe that all wisdom resides in the Australian regulators and that, from a New Zealand perspective, much of the TGA's consultations have the appearance of "our way or the highway". To the contrary, we consider there is much in the New Zealand processes that:

- are more firmly based on a risk/benefit approach;
- accord more and better with best practice in countries with which we compare ourselves; and
- more closely reflect the regulatory approach set out in the Commission's TOR guidance.

We ask the Commission so to find.

[16] More information about the consultation on the high level description of the joint agency is available at [http://www.anztpa.org/consultation/consult-anztpa-scheme-130108.htm]. A copy of the ASMI submission is available at [http://www.anztpa.org/pdf/submissions/consult-anztpa-scheme-130108-submission-asmi.pdf]

[17] Emphasis added.

Conclusions

The regulation of therapeutic products is a complex business. We would say present arrangements include obscurantist elements. In this submission, we have tried to give the Commission an overview. We have selected what seem to be the most important elements, as capable of improvement.

These areas include:

- **a necessary retreat from command and control to world's best practice;**
- **a respectful view of New Zealand arrangements to adopt and adapt what is best for the proposed joint agency;**
- **a determined Government push to adopt our proposed Self Care approach;**
- ***sensible* improvements in the scheduling system, based on a risk/benefit approach; and**
- ***sensible* improvements in the regulation of advertising of therapeutic products and effective early removal of the ban on advertising of some S3 products.**

ASMI will be happy to expand on this submission and to appear before the Commission, if desired.