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ASMI 2013 – 2014 Pre-Budget Submission

Introduction

The Australian Self-Medication Industry (ASMI) represents the manufacturers of non-prescription medicines, i.e. over the counter (OTC) and complementary medicines. ASMI welcomes the Treasurer's invitation to submit ideas to be considered for the 2013 budget.

ASMI acknowledges the tight fiscal position that the Government continues to face post-GFC but recognises the relatively strong overall position of the economy. Concurrent with the challenge of maintaining a responsible fiscal position comes the need for flexibility to respond to changing circumstances.

A balanced budget will address issues of major impact, particularly the changing demographics of the Australian population. The ageing population creates fiscal pressures due to the increasing burden of disease which will result in unsustainable public healthcare expenditure at current trends.

Improved access by Australians to non-prescription products supports the wider adoption of increased personal responsibility for health and wellbeing and an easing of the burden on overstretched GPs. Greater self care would improve health outcomes and provide considerable savings to the budget through better use of Commonwealth healthcare resources. We believe this would be consistent with the views of the Australian Preventative Health Taskforce which reported: *"Consumers should have access to tools to enable self-care and assist them to navigate the health system maze effectively."*

Improved access to well-evidenced medicines and increased options for self care are dependent on a range of reforms - removing regulatory impediments to support increased research and development and changes to the healthcare workforce arrangements to provide a greater role for pharmacists in primary healthcare.

Many of ASMI's members also have manufacturing operations in Australia producing a range of self care products for both the Australian and export market. As with much of the manufacturing industry in Australia, these operations are under pressure from the high value of the dollar, increased international competition (particularly from low cost sources) and rising domestic costs. Key to maintaining a competitive position as an investment destination will be an increased focus on research and development and this submission provides a number of proposals designed to stimulate research, at no cost to the Government.

These recommendations are considered in more detail below. Whilst recognising that not all of the recommendations fall within the responsibilities of the Treasurer, ASMI believes the adoption of the proposed suite of recommendations would deliver significant savings to the health portfolio as well as significant benefits for consumers and healthcare professionals as well as supporting a viable and responsible industry.

1 Overview

The Australian Self Medication Industry (ASMI) is the peak body representing sponsors of non-prescription medicines – over-the-counter (OTC) and complementary medicines. Its members make up 85% of the \$4bn self care market. Membership totals 60 companies and ASMI members employ approximately 17,000 people with exports estimated at \$600 million annually.

ASMI's primary strategic objective is to promote an increasing role for responsible self care, more broadly, and self-medication, more specifically, as part of an overall Australian health strategy. The concept of self care entails greater personal responsibility for maintaining health, preventing disease and taking an active role in the management of disease.

There is general recognition that self care is a vital resource of any healthcare system. For example, research conducted in the United States found that for every \$1 spent on OTC medicines, the U.S. healthcare system saves \$6 to \$7, providing \$102 billion in value each year. This includes \$77 billion in clinical cost savings (avoided doctor's office visits and diagnostic testing) and \$25 billion in medicine cost savings (lower-priced OTCs versus higher-priced prescription medicines). It is estimated that, at minimum over 10 years, this amounts to more than a trillion dollars in avoided costs. (Booz & Co in conjunction with CHPA *"The Value of OTC Medicine to the United States"* January 2012)

Australians already manage or treat a large proportion of their ailments without consulting a doctor. There is growing evidence to show that promoting self care leads to a number of benefits for the community and government through:

- improved general health and quality of life;
- prevention of disease;
- improved management and control of existing conditions;
- increased productive life of the individual;
- increased patient satisfaction;
- reduced use of general practitioners and hospital services; and
- reduced resource burden on government health and welfare services.

2 Making better use of scarce healthcare resources

ASMI believes there is scope to undertake a number of reforms to encourage responsible self care. This has the capacity to deliver considerable benefits in improved personal health, better utilisation of scarce health resources and a necessary change in patient behaviour over the medium term.

A study commissioned by ASMI found that 7% of all GP consultations involve the treatment of common (minor) ailments alone – the full time equivalent of up to 1,000 GPs. (ASMI paper September 2009 – *"The Potential Economic Impact of Expanded Access to Self-medication in Australia"*) When projected nationally it found a total of 25 million GP consultations annually, or approximately 96,000 consultations per day, involve the treatment of nothing more than a minor ailment.

Also, approximately 59% of minor ailments resulted in a prescription, suggesting almost 15 million prescriptions being provided for minor ailments on an annual basis.

Pharmacists are a vastly underutilised healthcare resource. Community pharmacists are ideally positioned as a good first port of call to seek advice on medicines or, when there is uncertainty, whether there is a need to see a doctor about a problem. Pharmacists know a lot about non-prescription medicines that can be used to treat common minor ailments. There is ample scope to relieve this workload on GPs by expanding the professional role of pharmacists in primary healthcare delivery as has been recognised in government policy.

Proposal 1 – Establish an Australian Self Care Alliance

ASMI proposes that the Government initiates, coordinates and maintains a systematic debate about self care as a fundamental element of public health policy through the establishment of a Self Care Alliance, which would include all key stakeholders - Government, consumers, healthcare professionals, health economists and industry.

The proposed Self Care Alliance could provide strategic guidance for building the evidence base to support policy decisions in relation to greater self care and identifying opportunities for more cost-effective healthcare delivery, e.g. by enabling pharmacists to play a greater role in the treatment of common ailments rather than relying on GPs as being the first call.

3 Increasing access to medicines to support greater self care

The major obstacles to greater self care lie in the regulatory area. ASMI believes that attaining the benefits of increased self care, with attendant improved health outcomes and reduced health expenditure, can be achieved at minor cost to the Commonwealth by addressing the following issues:

3.1 The approach to the regulation of non-prescription medicines

The benefits of non-prescription medicines go well beyond efficacy demonstrated in clinical trials, and are based in real life experiences which are harder to quantify or define. Because these benefits have generally not been well characterised, a tendency towards overemphasis on risk in regulatory decision making has emerged, without necessarily having a positive impact on public health.

Regulation requires a shift away from avoiding risk towards managing risk. An unduly risk-averse approach to health and safety can have the unintended consequence of preventing timely access to appropriate medicines. These are quite out of character with the commitment to removing unnecessary regulation.

Proposal 2 – Adopt an OTC-specific Benefit Risk Regulatory Model

Through its membership of the World Self Medication Industry (WSMI), ASMI has contributed to the development of a specific non-prescription medicines benefit-risk decision-making tool. This model has already been adopted in the UK and Canada and we propose the adoption of this model by the Therapeutic Goods Administration (TGA).



3.2 Conservative and risk-averse medicines scheduling environment

Expanding the professional role of pharmacists requires the tools which will allow them to assume a larger role in primary healthcare delivery. For example, increased access to medicines can be achieved through appropriate rescheduling (“switch”) of medicines from Prescription Only (Schedule 4) to Pharmacist Only Medicine (Schedule 3) or, in other cases, to Pharmacy Only (Schedule 2).

3.3 Restrictions on Schedule 3 advertising

These advertising restrictions are unjustified because they deliver no net public health benefit. In fact, the restrictions have a negative impact. They act to inhibit the ability of industry to make consumers aware of treatments which become newly available without a prescription. Consequently, consumers continue to consult GPs for conditions which could be safely managed by a pharmacist, and, as the study mentioned above indicated, it is highly likely these consultations would result in scripts being issued, further adding to unnecessary public health costs.

The combination of a risk-averse approach to scheduling and the restrictions on advertising presents major obstacles to increased access to medicines. There is no evidence of any detriment to public health and safety as a result of the more progressive approach adopted in comparable international jurisdictions, i.e. New Zealand and UK.

Proposal 3 – Establish best practice regulatory scheme through ANZTPA

The joint Australia New Zealand Therapeutic Products Agency (ANZTPA) provides a unique opportunity to pursue best practice regulation through harmonisation and adoption of the best of both worlds. It can enhance our competitive position in “the Asian Century” where members of the growing middle class are strong supporters of non-prescription medicines.

ASMI has been, and remains, a strong supporter of the proposed joint agency. Ever since this proposal grew out of the Trans-Tasman Harmonisation and Mutual Recognition initiatives, ASMI has made strong and positive contributions to the debate on a proposed joint agency.

We are concerned, however, about the prevailing attitude that the Australian regulatory scheme is the “gold standard” to which New Zealand needs to harmonise. The New Zealand scheme is more progressive in at least two respects: scheduling (“switch”) and the advertising of Schedule 3 (Pharmacist Only) Medicines.

Previously the two Governments adopted a policy in relation to the scheduling of medicines to harmonise to the least restrictive arrangements, unless a compelling case to the contrary could be made on public health and safety grounds. ASMI believes this policy should also guide the development of a single regulatory framework, without compromising public health and safety.



3.4 Impediments to industry growth and viability

Investment in research and development is necessary to underpin a growing and vibrant OTC and complementary medicines industry. But indications are that levels of innovation in Australia are below the industry's global peers.

Increased access to well-evidenced medicines is vital to support greater self care. The industry recognises the need to build the evidence-base supporting complementary medicines to meet the community's expectations. However, meeting these expectations will require significant investment by sponsors to generate sound scientific evidence.

Similarly, increasing access to OTC medicines through rescheduling from prescription status will require will investment to generate the regulatory data required to support applications.

The lack of incentive to invest to develop the science, where patents are not an option, is a well-articulated and potent suppressor of innovation in the sector. Currently there is no provision for market exclusivity, and where competitors benefit from the data generated by the innovator, the latter is placed at a significant commercial disadvantage. Data protection is a means by which an innovator's data are protected for a period of time from competitors; and this includes from a subsequent sponsor seeking similar approval for an equivalent therapeutic good.

Other jurisdictions, particularly the European Union and the United States, have data protection regimes that are quite favourable to sponsors and make Australia's look relatively restrictive by comparison.

Industry believes that a period of marketplace exclusivity, commensurate with the degree of innovation and investment, is required to recoup investment costs and, importantly, act as an incentive to research new therapeutic claims and products.

Proposal 4 – Implement appropriate IP protection provisions for non-prescription and complementary medicines

One possible solution would be to expand the existing data protection provisions in the Therapeutic Goods legislation to make provision for substances other than new substances. This reform would not require any budgetary outlay by the Commonwealth but would, in fact, be revenue positive for its encouragement of additional investment and employment.

It is important to note that the solutions proposed are intended to address issues of regulatory failure in relation to non-prescription and complementary medicines only and are not designed to impact on prescription medicines and the PBS. Industry would support measures to prevent any unintended consequences resulting from the introduction of these reforms

Summary

Whilst recognising that not all of the above recommendations fall within the responsibilities of the Treasurer, ASMI believes the adoption of the proposed suite of recommendations would deliver significant benefits for consumers, Government and industry. The adoption of the recommendations within this submission has the potential to reduce healthcare costs by providing the Australian population with greater options for self care and to deliver a more efficient, effective and sustainable healthcare system at minimal cost to the Commonwealth. These reforms would also support a responsible and viable non-prescription medicines industry.

