Australian Self Medication Industry Ltd.
ACN 607 233 116 ABN 55 082 798 952
Suite 2202, Level 22, 141 Walker Street,
North Sydney, NSW 2060
PO Box 764 North Sydney NSW 2059
Ph: +61 2 9922 5111 | Fax: 61 2 9959 3693
Email: info@asmi.com.au | www.asmi.com.au

Australian Self Medication Industry

2018-19 Pre-Budget Submission

Advancing consumer health through responsible self care

2018-19 Pre-Budget Submission

SUMMARY OF RECOMMENDATIONS

The Australian Self Medication Industry (ASMI) is the peak body representing the majority of Australia's $5.4 billion non-prescription medicine industry. This includes manufacturers and distributors of over-the-counter (OTC) medicines and complementary medicines.

Adoption of the recommendations contained in this pre-budget submission have the potential to reduce healthcare costs by providing the Australian population with greater options for evidence based medications as part of their self care. They could contribute to a more efficient, effective and sustainable healthcare system at no cost to the Commonwealth. These regulatory reforms would stimulate investment and innovation by the non-prescription medicines sector.

To enable this, ASMI recommends that Government should:

1. **Recognise self care as an integral element of a coordinated and comprehensive national health policy in Australia.**

   Greater self care can lead to better health outcomes and a more cost-effective healthcare system. The benefits of self care, particularly in the context of non-prescription medicines, are well documented in the literature.

2. **Develop a 'switch' agenda by proactively identifying future prescription to over-the-counter (OTC) switch candidates.**

   To promote greater self care, Government must consider improving consumer access to non-prescription medicines. Many medicines now commonly available OTC started out as prescription-only. A successful switch agenda should empower consumers, encourage industry to submit switch applications, and foster innovation in OTC medicines.

3. **Streamline approval for direct-to-consumer communications for OTC medicines.**

   Currently, Schedule 3 (S3) medicines cannot be advertised unless the manufacturer applies for and is granted an exemption. The current arrangement dis-empowers consumers and acts as a disincentive for industry to submit switch applications.

4. **Encourage switch applications by providing intellectual property protection.**

   Non-prescription medicines do not benefit from the same level of intellectual property protection as prescription medicines. This means if a sponsor invests in additional clinical research as part of their switch application, the research outcomes will be made public and can be used by competitors. This acts as a major disincentive for companies to pursue a switch application.

5. **Harmonise OTC labelling requirements with New Zealand.**

   Australia and New Zealand are small markets that benefit from supply of product across both markets. Lack of alignment on labelling requirements will ultimately impact patient access.

1. Introduction

1.1 About ASMI

The Australian Self Medication Industry (ASMI) is the peak body representing the majority of Australia's $5.4 billion non-prescription medicine industry.[i] This includes manufacturers and distributors of over-the-counter (OTC) medicines and complementary medicines, such as vitamin supplements.

Our industry is proud of the contribution we make to the health of Australians and the Australian economy. Collectively, we:

- Employ over 18,000 Australians, including in highly skilled roles such as advanced manufacturing and R&D
- Generate approximately $2.1 billion annually in local manufacturing revenues[ii]
- Export an estimated $2 billion each year[iii]
- Provide consumers with choice and access to approximately 16,000 non-prescription medicines that are on the Australian Register of Therapeutics Goods (ARTG) [iv]

And every $1 spent by consumers on the top 8 non-prescription product categories saves the Australian economy $4.[v]

1.2 Australia's Healthcare System – Challenges & Opportunities

Australia's healthcare system is under increasing pressure. A shifting burden of disease and an aging population continue to put pressure on the system.

Policymakers have recognised that something must change to ensure our system is sustainable both now and into the future. In addressing this challenge, the 2014 Intergenerational Report, 2017 Productivity Review and numerous other reports all highlight the importance of reorientating the healthcare system towards prevention. Preventative Health is also one of the four key pillars of Government's Long Term National Health Plan.

ASMI strongly supports Government's Long Term National Health Plan and applauds Government for recognising the importance of preventative health. A key component of preventative health is empowering consumers to play a more active role in managing their own health. This includes providing access to a broad range of consumer healthcare products, such as non-prescription medicines, as well as information, to promote responsible self care.

2. The Importance of Self Care

Recommendation 1:

Government should recognise self care as an integral element of a coordinated and comprehensive national health policy in Australia.

Self care is as an integral element of a coordinated and comprehensive national health policy. Self care refers to the activities individuals, families and communities undertake on their own behalf with the intention of preventing disease, enhancing health and treating minor illness.

Greater self care can lead to better health outcomes and a more cost-effective healthcare system. The health and economic benefits of self care, particularly in the context of non-prescription medicines, are well documented in the literature:

- Research undertaken by the McKell Institute estimates that increasing the use of vitamin D and calcium supplementation by at risk groups, as well as increasing the uptake of pregnancy vitamins by low income mothers, could save the Australian health system over $180 million per year.[vi]
- Research conducted by the Macquarie University Centre for the Health Economy (MUCHE) estimates that there would be an additional cost to the health system of $3.86 billion each year if the eight largest categories of OTC medicines were not available and consumers had to go to a GP to get a prescription for them. This cost increases to over $10 billion per annum if the *indirect* costs of visiting a doctor (e.g. productivity losses) are taken into account. [vii]
- Research[viii] conducted by Booz & Co. in the U.S. found that for every US$1 spent on OTC medicines, the U.S. healthcare system saves $6 to $7. A similar study conducted by MUCHE in 2014 found that every AUD $1 spent on the eight categories of the most commonly used OTC medicines in Australia produces a saving of more than AUD $4.[ix]
- Research undertaken by Precision Health Economics estimates that self medication contributes $120 billion in healthcare savings globally.[x]

Self care should be recognised as an integral element of a coordinated and comprehensive national health policy in Australia. See Appendix 1 for further information on the Role of Self Medication in Responsible Self Care.

3. International Best Practice Medicines Scheduling Framework

3.1 Switch Agenda

Recommendation 2:

Government should develop a 'switch' agenda by proactively identifying future prescription to OTC switch candidates.

To promote greater self care, Government must consider improving consumer access to non-prescription medicines.

First and foremost, better consumer access to non-prescription medicines is not possible without a best practice medicines scheduling framework.[xi] We were therefore pleased when Government announced it would review Australia's Scheduling Policy Framework in line with recommendations made by the Expert Panel Review of Medicines and Medical Devices Regulation. ASMI supports a transparent, streamlined national scheduling system that appropriately balances risk and benefit.

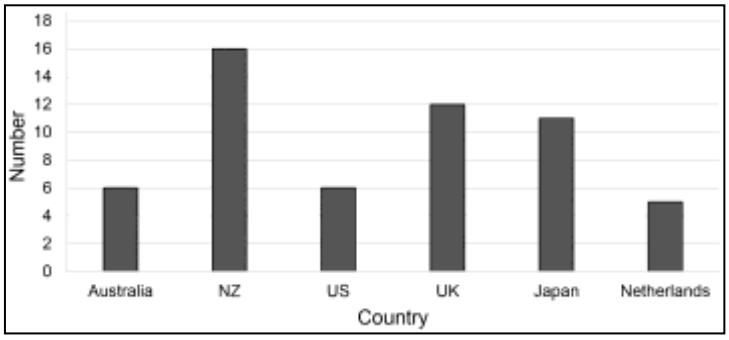
ASMI submits that a key component of a best practice medicines scheduling framework should be a progressive 'switch' agenda. Switch is the down-scheduling of a medicine e.g. from prescription-only (Schedule 4) to OTC (Schedule 3).

Schedule 3 medicines are used to treat a range of everyday conditions that either do not require medical diagnosis or only require initial medical diagnosis and no close medical management. They are therefore available OTC (i.e. without a prescription). Examples include medicines that treat cold sores, conjunctivitis, mouth ulcers and nausea/vomiting associated with migraine and travel sickness. All

Schedule 3 medicines have been deemed "substantially safe with pharmacist intervention" by the TGA.

Many medicines now commonly available OTC started out as prescription-only. Examples include aciclovir for cold sores and nicotine replacement therapy for smoking cessation. In fact, Australia once led the world in switch. In recent years, however, the frequency with which prescription drugs have been down-scheduled in Australia has dropped well below that of our international peers.

Figure 1: Progressive Rx to OTC Switch Activity 2003-13[xii]



To address this lag, ASMI believes that Government, in concert with relevant stakeholders, should develop a formal 'switch' agenda by proactively identifying future prescription to OTC switch candidates.

There are currently a number of prescription-only medicines that could be considered candidates for a switch in Australia. These include low-dose statins for cholesterol, triptans for migraine, antibiotics for urinary tract infection and chlamydia, oral contraceptives and erectile dysfunction medicines. Medications in these categories meet the criteria of having a good efficacy and safety profile that have been demonstrated over time to address minor ailments that may be diagnosed and managed without medical intervention. Many of these are also already available OTC or are in the process of being transitioned to OTC in New Zealand, which has a similar healthcare system and regulatory framework to Australia.

In developing the agenda, ASMI recommends Government consider:

- The switch agenda model adopted by the U.K. Government in 2012
- MUCHE's framework for economic evaluation of switch[xiii]
- Recent research undertaken by Griffith University, which reviewed Australian pharmacists' perspectives on medicines suitable for switch.[xiv]

3.2 Incentivising Switch

A successful switch agenda should empower consumers, encourage industry to submit switch applications, and foster innovation in OTC medicines.

Direct-to-consumer communications

Recommendation 3:

Government should streamline approval for direct-to-consumer communications for OTC medicines.

In Australia, the default regulatory position is that Schedule 3 medicines cannot be advertised, unless the manufacturer applies for and is granted an exemption. ASMI submits that this approach focuses almost exclusively on risk with little consideration of benefit. In the interest of raising consumer awareness of safe and proven therapeutic products that are already available OTC, ASMI proposes that these restrictions be revised.

Take, for example, chloramphenicol, which is used for bacterial conjunctivitis (an easily identified condition) common in young children. Chloramphenicol is available without a prescription, but it cannot be advertised. Because it cannot be advertised, parents are often unaware it is available OTC at their local pharmacy. This means they spend unnecessarily time and money visiting a GP seeking treatment for their child. This arrangement only serves to dis-empower consumers because 'they are not allowed to know'.

The restrictive direct-to-consumer communications framework also acts as a disincentive for industry to submit switch applications. In many cases, and under current policy settings, companies concluded that a switch is not commercially viable because sales might actually decrease. If doctors no longer prescribe the medicine, but consumers do not realise they can access the medicine from their pharmacist, then demand shrivels.

ASMI acknowledges that the TGA is currently reviewing the advertising of OTC medicines, in line with recommendations made by the Expert Panel Review of Medicines and Medical Devices Regulation. Our submission to the TGA's consultation in May argued that the present restriction on advertising of S3 medicines is:

- Not supported by any published evidence
- Based on outdated and restrictive guidelines with unclear criteria that have not been updated for more than 15 years[xv]
- Inconsistent with the National Medicines Policy.

ASMI proposed an alternative model for direct-to-consumer advertising of Schedule 3 medicines, whereby:

The default regulatory position would allow advertising of these medicines, with certain exceptions, i.e. a risk-based approach to Schedule 3 advertising

- Provision would be made for these exceptions based on public interest and safety criteria
- Regulatory controls would ensure compliance.
- Consumers would be encouraged to consult their pharmacist on the medicine's suitability

ASMI's proposal is aligned with international best practice and supported by the current literature.[xvi]

Intellectual Property

Recommendation 4:

Government should encourage switch applications by providing intellectual property protection.

Under the current system, non-prescription medicines do not benefit from the same level of intellectual property protection as prescription medicines. For example, there is currently no provision for data protection in relation to regulatory data generated for a switch application. This means if a sponsor invests in additional clinical research as part of their switch application, the research outcomes will be made public and can be used by competitors. Given such research can cost as much as $20 million, this acts as a major disincentive for companies to pursue a switch application.

To encourage switch applications, Government must provide appropriate intellectual property protection for companies. ASMI recommends Government review the United States' experience in this area. The Hatch/Waxman Act establishes a period of five years of data exclusivity for new chemical entities and additional three year periods for new claims on existing products where new clinical data was essential for the approval of the application. This has been a major driver of the prescription to OTC switch process in the United States.

4. Labelling Requirements

More and more, companies require harmonised packaging across markets to justify making medicines accessible to consumers.

Recommendation 5:

Government should harmonise OTC labelling requirements with New Zealand.

TGA and Medsafe are currently implementing a new process for labelling medicines, following years of consultation. ASMI remains concerned that this new process, however, has a number of unintended consequences which could ultimately impact patient access.

Specifically, the new Therapeutic Goods Order for labelling (TGO92) does not yet align with labelling regulation in New Zealand. Australia and New Zealand are small markets that benefit from supply of product across both markets. Lack of alignment on labelling requirements will:

- Reduce patient access, as certain products will become untenable for export
- Increase prices for consumers, as manufactures will be required to make a considerable investment in separate packaging under reduced economies of scale.

These concerns have been highlighted in Government's Regulatory Impact Statement, and although sponsor companies have been told that there are options to maintain a harmonised label with New Zealand, these options are neither practical nor workable. To date, we are unaware of any such exemptions granted.

ASMI therefore requests that Government make a policy commitment with agreed timeframes to attain an alignment with Medsafe on the proposed changes to the labelling order so that Australian labels can remain harmonised with those in New Zealand.

Appendix 1

The Role of Self Medication in Responsible Self Care

References

[i] IRI Scan Data Total OTC Market (defined by ASMI) Pharmacy and Grocery Channels combined, 2016 FY

[ii] IBIS Pharmaceutical Product manufacturing in Australia, March 2014. IBIS World Pty Ltd.

[iii] ASMI Industry Estimate

[iv] TGA Half Yearly Performance Report (March 2015)

[v] *The Value of OTC Medicines in Australia*, Macquarie University Centre for the Health Economy, March 2014.

[vi] *Picking the low-hanging fruit- achieving a more equitable and sustainable health care system*, McKell Institute, WSMI GA 2017

[vii] *The Value of OTC Medicines in Australia*, Macquarie University Centre for the Health Economy, March 2014.

[viii] *The Value of OTC Medicine to the United States*, Booz & Co in conjunction with Consumer Healthcare Products Association, January 2012.

[ix] *The Value of OTC Medicines in Australia*, Macquarie University Centre for the Health Economy, March 2014.

[x] *Evidence Base for the Economic Value of Self Care*, Precision Health Economics (PHE), WSMI GA 2017

[xi] Scheduling is a national classification system that controls how medicines are made available to the public. Medicines are classified into Schedules according to the level of regulatory control over the availability of the medicine that is required to protect public health and safety.

[xii] *Widening Consumer Access to Medicines through Switching Medicines to Non-Prescription: A Six Country Comparison*, Gauld et al

[xiii] *Health Economic Framework to Inform Prescription to OTC Switch*, Dr Bonny Parkinson, Macquarie University, WSMI GA 2017

[xiv] *Australian Pharmacy Perspectives on Demand and Readiness for Increased Non-Prescription Availability of Medicines*, Griffith University 2017

[xv] NCCTG Schedule 3 advertising guidelines, November 2000 https://www.tga.gov.au/publication/schedule-3-advertising-guidelines

[xvi] *Advertising Impact on Consumer Self Care Behaviour*, Dr Isabell Koinig, University of Klagenfurt, Austria, WSMI GA 2017; *Role & Impact of Consumer Advertising on Pharmacist-only Medicines*, Prof Rosalie Viney, University of Technology, Sydney, WSMI GA 2017; *Estimating the Impact of Schedule 3 Consumer Advertising*, University of Technology Sydney Centre for Health Economics Research and Evaluation (CHERE), November 2016