



AUSTRALIAN SELF-MEDICATION INDUSTRY
BETTER HEALTH THROUGH RESPONSIBLE SELF-CARE

To: grocerypricesinquiry@acc.gov.au

Grocery Prices – submission to the ACCC Inquiry

Dear Inquiry

The Australian Self-Medication Industry is pleased to provide the attached submission for your inquiry.

If you wish to have further advice or information, please contact me.

Yours faithfully

Juliet Seifert
Executive Director



AUSTRALIAN SELF-MEDICATION INDUSTRY
BETTER HEALTH THROUGH RESPONSIBLE SELF-MEDICATION

GROCERY PRICES

Submission to the ACCC Inquiry

by

Australian Self-Medication Industry

March 2008

Contents

Executive Summary		iii
This submission		1
The Therapeutic Goods market		1
Regulation and classification of medicines		1
<i>Registered or Listed?</i>	1	
<i>Scheduling of “poisons”</i>	2	
<i>GST</i>	2	
<i>“Switching”</i>	3	
Competition in the medicines market		3
Responsible self-medication: self-care		4
GST		4
Conclusions and Recommendations		5

Executive Summary

- Australian Self-Medication Industry (ASMI) represents the manufacturers and sponsors of non-prescription medicines in Australia. The industry has an annual turnover of about \$2bn.
- Recognising that the main focus of the inquiry is on food prices, this submission briefly outlines the regulatory and taxation issues affecting the sale of medicines. ASMI is happy to provide further advice or information if required.
- The “scheduling” of medicines controls what may be sold outside pharmacies. “Unscheduled” medicines largely include low-risk products which people buy to help with the treatment of common ailments.
- ASMI believes that the competition issues in respect of “unscheduled” medicines are similar to those in the food and other grocery/supermarket outlets.
- Competition will be enhanced in the medicines market if-
 - there is the widest possible access to “over-the-counter” medicines, consistent with the principle of responsible self-medication; and
 - there is a recognition among public health policy-makers that ready access to self-medication will advance the Government’s emphasis on preventative rather than curative healthcare.
- There is an opportunity to reduce the cost to working families of their medicines if the GST did not apply to any medicine listed on the Australian Register of Therapeutic Goods.
- The regulatory regime for OTC medicines should be reviewed consistent with the maintenance of public health and safety.

This submission

This submission to the ACCC inquiry into grocery prices is from the Australian Self-Medication Industry (ASMI). ASMI represents Australian manufacturers and sponsors of non-prescription medicines.

At Attachment 1 is some background information about ASMI, its membership and its policy objectives. Further information or clarification could be provided if required.

The Therapeutic Goods market

As set out in more detail below, Australian therapeutic goods regulatory arrangements allow some non-prescription medicines to be sold in outlets other than pharmacies. This category of goods will usually appear on supermarket or store shelves near or with “personal care” products, many of which are regulated as cosmetics¹ rather than as “therapeutic goods”.²

Total annual turnover of non-prescription medicines is \$2.3 bn. Products not sold in pharmacies account for \$.06 bn, or 38% of this market.

ASMI represents manufacturers and sponsors of two broad categories of medicines:

- “Over-the-counter” (OTC) – mainly proprietary pharmaceutical lines and more likely to be sold in pharmacies only; and
- “Complementaries” – vitamins, minerals and herbal supplements – sold variously in health-food stores, pharmacies or grocery-supermarket.

Regulation and classification of medicines

Registered or Listed?

The Therapeutic Goods Act (“the Act”) allows medicines to be approved for sale by means of entry on the Australian Register of Therapeutic Goods (“ARTG”) either as

- a Registered product³; or
- a Listed product.⁴

In both cases, goods must satisfy safety and quality standards. In addition, AUST R goods must meet stringent efficacy requirements; AUST L goods must hold efficacy data for checking in the event their therapeutic claims require testing.⁵

¹ See Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991.

² Therapeutic Goods Act, Regulations and related Legislative Instruments.

³ AUST R appears on the label.

⁴ AUST L appears on the label.

⁵ This will usually happen if someone makes a complaint about claims made in an advertisement. The Complaints Panel and/or the TGA may then requisition the efficacy data and assess its validity.

Scheduling of “poisons”

Under a complex Commonwealth-State regulatory scheme, the National Drugs and Poisons Schedule Committee (NDPSC) draws up a Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). It classifies substances into Schedules which limit access to stated categories of supplies. The higher the Schedule, the more restricted the access.

Substances which are medicines are classified in Schedules 2, 3, 4, 8 and 9, are shown in the box.

Medicine Schedules
S9 – Prohibited drugs
S8 – Dangerous/restricted drugs
S4 – Prescription-only supply
S3 – May only be sold by a pharmacist
S2 – May only be sold in/from a pharmacy
Unscheduled – Open sale (“GSL”)

All scheduled medicines must be registered (AUST R). It follows that S4, S3 and S2 products must be sold in pharmacies only. On the other hand, a few unscheduled products are also required to be Registered – notably analgesics in small packs. These can be sold in open sale, but larger pack sizes remain a pharmacy monopsony.

GST

GST has been payable on some medicines, but not others, since the legislation was first enacted. The following table summarises the present situation.

GST on medicines		
	GST-free	GST payable
Pharmacy:	S4, S3 and S2 medicines	All other unscheduled products,
GSL:	Unscheduled small-pack analgesics (Aspirin, Paracetamol, Ibuprofen)	e.g.-
	Sunscreens SPF15+	Vitamins
	Folate supplements (not including iron)	Minerals
	Tampons*	Herbals
	Nicotine-based smoking cessation products	Cough/cold preparations
		Mouth washes
		Dermatologicals
		Disinfectants
		Hair treatment products
Note: Tampons are classified under the Act as “devices” and are thus strictly speaking not medicines		

The list of unscheduled products which are GST-free has no rational basis. There are many unscheduled products which provide at least as many public health benefits as do those in the short list in the box. **ASMI has always proposed that all products on the ARTG should be GST-free, irrespective of what restrictions on access any of them may attract.**⁶

“Switching”

From time to time, the NDPSC decides that certain substances may be down- or up-scheduled. Thus a prescription medicine (S4) may be re-scheduled as OTC (S3) or an S3 to S2. Importantly for the present enquiry, it is not unknown for scheduled substances to be de-scheduled. At that point, products become eligible for lawful sale in non-pharmacy outlets.

The most recent notable cases of de-scheduling were

- down-scheduling of small-pack ibuprofen, so that this product then competed with aspirin and paracetamol; and
- down scheduling of smoking-cessation products (one might imagine these as now competing with cigarettes).

In both these cases, it was necessary for the sponsors to go through an arduous process to obtain the agreement of the nine governments party to the GST Agreement to the grant of GST-free status.

ASMI considers that, at the very least, a product which is down-scheduled to GSL should automatically retain its GST-free status; and that the legislation should be amended accordingly.

Competition in the medicines market

We apprehend that those medicines in respect of which pharmacy enjoys a regulatory-imposed monopsony, are outside this inquiry’s terms of reference. As is implicit in the account of regulatory and tax arrangements given above, however, down-scheduling of some products, and/or reform in the GST regime, could affect the mix of factors influencing the prices of some products. ASMI is unable to speculate on the exact probable effects. Much of the relevant information is not in the public arena or known to our membership. Also, the market effects of various changes that might be envisaged could vary greatly, depending on the products in question.

As for products that are now unscheduled, ASMI notes that their situations in supermarkets and the like are comparable with those of foods, cosmetics, household cleaners and other products. The competition is between brands; ASMI member-companies compete for shelf-space and reach arrangements with retailers in accordance with their own commercial priorities.

Our members have noted, however, a tendency to develop “house” brands by the larger supermarket chains. This practice inevitably drives down wholesalers’ margins. A point could be reached where well-known medicine brands might

⁶ See p.4 below.

disappear from the market, including from supermarket shelves, simply because continuing supply for the prices offered will be uneconomic.

This inquiry will no doubt consider whether this degree of vertical integration helps or hinders competition and thus whether it keeps prices lower or drives them higher than would otherwise be the case.

Responsible self-medication: self-care

ASMI has always advocated the minimum regulation necessary to protect public health and safety and maximum public access to our products to promote competition. ASMI would like to see the regulatory authorities take a less risk-averse approach to their decisions about access. We would like to see formal processes in place designed to assess risk against benefits. The latter should include, in our view, not just medicinal efficacy, but also amenity and convenience for the consumer and the maximum opportunity for competition in a market with the least practicable regulation.

In keeping with these principles, ASMI has developed, together with like-minded industry groups overseas, the idea of self-care. The detailed elements of this approach are set out in our policy paper, reproduced at Attachment 2.

The Government's policy approach to health is consistent with a greater emphasis than in the past on a preventative approach. That is, the maintenance of wellness rather than the curing of illness should be the first line in public health policy. In this approach, people's access to medicines includes access to a wide range of products which are offered to the public to avoid or avert illness. ASMI considers that it is in the interests of public health and wellness for the maximum access and greatest competition to obtain.

ASMI's studies of consumer attitudes, and our members' own commercial experience, confirm that consumers of medicines are very conscious of the choices they make. They are neither children nor fools. Often these decisions rest with the female leader in the family. Typically, she will have relied on a wide range of sources of information in making the family's self-care choices. These include the family doctor and the local pharmacy, but extend more broadly these days to the internet, lifestyle magazines ("advertorials") and straight-out advertising (in all media), not forgetting word of mouth.

ASMI believes that the COAG Principles on Good Regulation should apply with equal force to the regulation of medicines. That is, it should be for the authority proposing the restriction on competition to show why it is needed; not on the business affected to show why it is not. As well, rigorous cost/benefit assessment should be applied in the case of any new regulatory restriction to be applied to access to OTC medicines.

GST

The complicated and irrational situation on GST on medicines was described above. In ASMI's view, it is neither equitable nor rational to tax products which people use to maintain their health but not to tax those (such as prescription medicines) used to curing illness.

The GST was removed from medicine products – as ASMI has long advocated – there would be an immediate 10% cost reduction in a range of medicines which people need and use regularly. While small, such a reduction could have a small, but significant effect on working families' budgets. It would put downward pressure on prices at a time when the authorities should be doing everything possible to fight inflation.

The cost to revenue – which goes to the States and Territories – is estimated at around \$200m/yr. At a time when there are strong fiscal policy reasons to reduce public outlays, such a revenue loss is more than reasonable.

ASMI recommends that the inquiry find that removing the GST on all medicines entered on the ARTG would benefit working families and promote the Government's preventative health agenda.

Conclusions and Recommendations

Medicines that can be sold in other than pharmacies exhibit the same characteristics – for the purposes of this inquiry – as other lines on sale in groceries or supermarkets.

ASMI would like to see maximum access by the public to OTC medicines, consistent with principles of public health and safety.

We recommend that this inquiry find that it is in the interests of consumers that the regulatory regime for OTC medicines to be the minimum consistent with public health and safety.

ASMI also recommends that this inquiry find that costs to consumers can be reduced by removal of the GST on all therapeutic goods entered on the ARTG.

About ASMI



ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products in Australia. ASMI also represents related businesses including advertising, public relations, legal, statistical and regulatory consultancy companies and individuals.

ADVOCACY, REPRESENTATION and INFORMATION

Our purpose is to promote the best interests of our members through negotiation, debate and co-operation with a wide range of stakeholders in our own region and around the world. We also gather the best and most current information from diverse sources in order to keep our members informed of the latest developments in the consumer health care products industry.

ASMI is a member of the World Self-Medication Industry (WSMI) and our President and Executive Director sit on the Board of that organisation. WSMI is a non-government organisation made up of over 50 member associations around the world, with affiliations to the World Health Organisation.

ASMI VISION

Better health through responsible Self Care.

ASMI MISSION

ASMI—the voice of the consumer Self Care products industry, driving a credible and expanding evidence-based self-medication market to generate cost-effective health solutions and improved public health outcomes.

ASMI VALUES

- Drivers of change through member contribution and industry interaction.
- Best practice in governance and service.
- Committed to representation by consumers.
- Consistent in policy and action.
- A learning organisation committed to competency development.

SELF CARE: THE FOUNDATION FOR A HEALTHY AUSTRALIA

The concept of Self Care lies at the heart of ASMI's vision for a healthy Australia: the vision of a nation where individuals and families choose to maintain good physical and mental health using a range of strategies including regular exercise, healthy eating and the appropriate use of self-medication to treat and prevent illness.

There is growing evidence, including research sponsored by ASMI, to show that effective Self Care within a community can help to prevent disease, manage existing conditions and improve the quality of life and general health of the population. As a result, the economic burden on government health and welfare bodies can be considerably reduced.

ASMI believes that the benefits of Self Care can be realised through the formation of strong partnerships between industry, government, consumers, health care providers and other stakeholders as well as through scientific and economic research. We will continue to build our relationships and support the development of an evidence-based platform which will give Self Care a significant place in Australian health management.

For a list of ASMI Members, see overleaf



BETTER HEALTH THROUGH RESPONSIBLE SELF CARE



ASMI Members



Ordinary Members

Allergan Australia
Aspen Pharmacare
Bayer Healthcare Consumer Care
Biological Therapies
Boehringer Ingelheim
C B Fleet Co (Australia)
Catalent
Church & Dwight Australia
Combe International
Ego Pharmaceuticals
Flordis
Galderma
GlaxoSmithKline Consumer Healthcare
H W Woods
Johnson & Johnson Pacific
Mentholatum Australasia
Nestle Australia
Nycomed
Novartis Consumer Health Australasia
Probiomics
Procter & Gamble Australia
Reckitt Benckiser
Roche Products
Sandoz
Sanofi-aventis Australia New Zealand
Schering-Plough
Smith & Nephew
Stiefel Laboratories
Stirling Pharmaceuticals
Symbion Consumer
Wyeth Consumer Healthcare

Associate Members

ACNielsen Australia
Agilent Technologies Australia
Anthea Steans Consulting
Archer Emery & Associates
AZPA International
BASF (Vic)
Bronson & Jacobs
Clare Martin & Associates
Clayton Utz
Contract Pharmaceutical Services of Australia
Curtis Jones & Brown Advertising
Engel, Hellyer & Partners
Euro RSGC Life
Freehills
H&T
IMS Health Australia
Kendle
Labmark
Lipa Pharmaceuticals
Love Communications
Minter Ellison
National Pharmacies
Oz Pharma Contracting & Consulting
Palin Communications
Pathway International
Regulatory Concepts
Remedies
Scental Pacific
Singleton Ogilvy & Mather
Synovate Aztec
Sue Akeroyd & Associates
Technical Consultancy Services
The Sales Factory
Thomson Playford
URSA Communications



BETTER HEALTH THROUGH RESPONSIBLE SELF CARE



Australian Self Medication Industry
Suite 2202, Level 22, 141 Walker Street, North Sydney NSW 2060
PO Box 764, North Sydney NSW 2059
Telephone: +61 2 9922 5111 Facsimile: +61 2 9959 3693
www.asmi.com.au

Attachment 2



AUSTRALIAN SELF-MEDICATION INDUSTRY

BETTER HEALTH THROUGH RESPONSIBLE SELF-CARE

Self-Care in Australia

The foundation for a healthy nation

What is Self-Care?

Self-care is a personal choice in health maintenance; it is the extent to which an individual, family or community engages in any activity with the intention of improving health, preventing disease, managing conditions, and restoring health.

Encompassing a broad spectrum of behaviour, self-care includes all health decisions consumers make for themselves and their families to maintain a good level of physical and mental health. These include maintaining physical fitness and good health to preventing disease or managing conditions, using self-medication to treat and prevent illness, and managing one's health after discharge from tertiary health care.

Self-care may be used alone (treating a mild headache), or may be used in collaboration with professional care (treating hypertension, see Figure 1). The Australian Self-Medication Industry (ASMI) believes that fundamental to the success of self-care is the formation of strong partnerships between governments, industry, consumers, health care providers and other interested stakeholders.

The Rise of Self-Care

The consumer is a rising power in Australia. Demanding greater information, choice, and responsibility, Australians are ready to take control of and manage their health. Increased media coverage, greater access to resources and increased education have all sparked a shift in attitude for many Australians. As a result, Australians are spending over \$900 millionⁱ a year on herbal medicines, vitamins and supplements, while 500,000 people in NSW alone (1.6 million Australia wide) have joined one of the state's 450 health clubs.ⁱⁱ

However, the message is not reaching all Australians, and more can still be done to raise the profile of self-care in the community. The prevalence of certain high health risk factors is on the rise in Australia. 44% of all Australians are inactive, while 62% of Australian males were classified as overweight in the 2004-05 National Health Survey, rising from 58% in 2001 and 52% in 1995. The proportion of females overweight or obese rose from 42% in 2001 to 45% in 2004-05. Over 77% of adults have at least one or more long term medical condition.ⁱⁱⁱ

These risk factors contribute to a myriad of resulting conditions; some of those identified by the National Health Priority List have been highlighted alongside their self-care solution in Appendix 1.

Did you know?

- **Total spending on health was \$87.3 billion in 2004/2005**
- **Up \$8.2 billion from the previous year**
- **Government picked up 68.2% or about \$59.4 billion of that cost^{iv}**

There is growing evidence to support the notion that promoting self-care leads to a number of benefits for the community and government through:

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

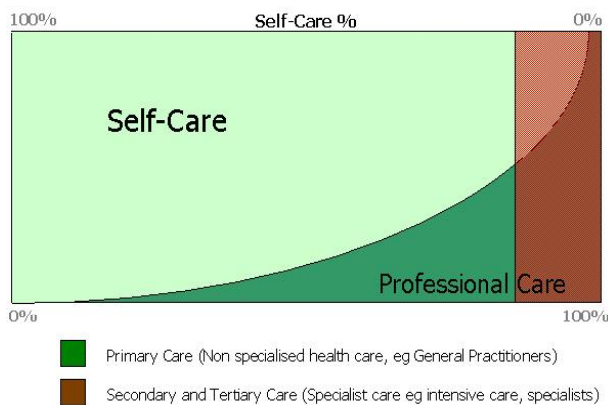


Figure 1: The Self-Care Spectrum

Self-Care in the Australian Context

Currently Australia does not have a comprehensive health policy in place. That is, a policy that examines health beyond simply the realm of health care (treating illness) but also all the factors contributing to the overall health of the nation:

- Family Income/Wealth
- Education
- Social support
- Working conditions
- Environment
- Biology/genetics
- Health services
- Childhood development
- Personal health activities and life skills

A comprehensive health policy recognises the effects of these health determinants on

health outcomes and allocates resources appropriately. The Ottawa Charter on health promotion (WHO, 1986) suggested that health policy should encompass all the legislative, fiscal, taxation, and organisational measures required in coordinating action that produce good health.

While there are several health promotion initiatives in operation, a more directed and organised approach is required. Official recognition of self-care as a fundamental means of nurturing the health of all Australians is essential.

Australia's Indigenous Population

The Australian Commonwealth Government has identified Aboriginal and Torres Strait Islander populations as ones of major health concern.

Indigenous peoples are generally more likely to develop conditions contained in the Health Priority Areas than non-indigenous populations, they are for example, 2.7 times more likely to develop cardiovascular disease and 8.3 times more likely to develop endocrine diseases such as diabetes.^v

The prevalence of certain risk factors such as smoking and obesity is also higher in indigenous populations, areas an integrated approach to self-care can significantly address. ASMI believes self-care can play a vital role in the effective delivery of important government strategies such as the *Health for Life Programme* to these populations.

Australians Living Dangerously

The report, *Living Dangerously – Australians with multiple risk factors for cardiovascular disease (AIHW, Feb 2005)* says that;

- 9/10 Australians have at least 1 risk factor of cardiovascular disease, most have at least 2
- Poor activity and diet are the most prevalent
- People of most disadvantaged socioeconomic groups are more likely to have 3 or more risk factors.

Conclusion: “There is great scope for the improvement of the health of Australians”^{vi}

There is a great deal of research from many parts of the world suggesting that self-care can play a vital part in building a sustainable, patient-orientated health care system. Such a system would involve:

- greater State and Federal cooperation in promoting self-care initiatives and making sure they are taken up;
- nationwide awareness campaigns inclusive of all Australians; and
- support and information provided to health care collaborators such as doctors, pharmacists and nurses to assist them in dispensing appropriate self-care advice.

Supporting Self-Care

Providing an environment conducive to self-care is everyone’s responsibility. It involves equipping consumers with the choices, skills and tools necessary to make their own health care decisions appropriately, confidently and effectively. In addition, industry and health providers require the tools, training and support necessary to assist all Australians appropriately.

Self-care needs to be presented to the population from many angles and must be inclusive of all demographics. Effective methods of promoting self-care include:

- Responsible, effective and accessible information and advice available in a variety of languages
- Training the individual and community from an early age in the importance of self-care through:
 - Physical Education
 - First Aid
 - Safe use of medicines
 - Personal hygiene
 - Treating minor ailments
 - Preventing illness
- Training of practitioners in providing self-care support
- Encouraging a change of mindset within health care professionals to one supportive of self-care through education
- Condition management skills for chronic sufferers with the assistance of the relevant condition associations and groups
- Individual care plans, and professionals to assist in their implementation and maintenance
- Educating consumers on the roles of health care professionals and dispelling myths and misconceptions
- Collaboration with cultural and religious groups and associations
- Lifestyle advice through training, campaigns, and media
- Encouragement of a collaborative health care environment
- Facilitating the switch of appropriate prescription-only medicines to over-the-counter
- Ensuring self-care products, such as OTC and complementary medicines provide adequate consumer information
- ASMI believes firmly that a consumer healthcare product is more than “just the pill” but rather encompasses all the packaging and information that ensures the therapeutic good can be safely and effectively used
- Provisions for a subsidised annual ‘check-up’ with a general practitioner to identify Australians at risk and place them on a preventative self-care plan
- Empowering pharmacists and nurses with additional responsibility. (For

example, allowing pharmacists or nurses limited prescribing and issuing of medical certificates valid for 1 – 3 days)

- Incentives through private health insurance to encourage engagement of nutritionists, naturopaths and other complementary healthcare professionals to help develop strategies for longer term holistic health maintenance.

Self-Care Fact Cards

The Pharmaceutical Society of Australia produced a series of 81 self-care fact cards educating the consumer on common conditions and what measures can be taken to manage them;

- 97% of consumers were satisfied with the cards
- *“I find the Fact Cards informative and helpful, and handy to keep for reference”.*
- *“I prefer to go to a chemist than to a doctor. The Fact Cards provide reassuring information and you can go to the doctor if the information on the Cards suggests this option”.*^{viii}

Health Care “Collaboration”

A cornerstone of effective self-care practice is ensuring the individual feels involved and in control in the management of his or her own health. Doctors, complementary health care professionals, pharmacists and nurses, *Health Care Collaborators*, should be encouraged to communicate with those seeking health care and with each other in providing the health service. Australians should be actively engaged and consulted about their options, and only with their informed approval should treatment decisions be made collectively.

An Integrated Health Approach

Recognising that every Australian’s situation is unique and acknowledging that

everyone holds a high degree of responsibility for their own health, an integrated health approach involving self-care focuses on a consumer’s overall health status in their own context. This involves the doctor working with the patient to maintain health and prevent ill health by factoring in the individual’s social and environmental context. Integrated health is an acknowledgement that not one therapeutic practice can hold a complete monopoly on the diagnosis and treatment of all conditions, but rather that partnerships need to be formed to ensure all Australians receive an optimal standard of care.

A GP may, for example, prescribe a cholesterol-lowering medication for a patient and in addition, under an integrated health approach, would identify the underlying factors contributing to the person’s condition. These factors might include poor food choices, obesity, stress, or inactivity. An integrated approach could see the doctor recommend consultation with complementary practitioners, advice on complementary and OTC medicines or suggest lifestyle changes and other self-care measures.

This sort of cooperation is already taking place. The Prince of Wales Foundation is a body operating in the United Kingdom with the primary directive to forge partnerships between conventional and complementary bodies to encourage an integrated approach to health. More information about integrated health and the Foundation’s activities can be found at their website. (<http://www.fihealth.org.uk>)

Combination Therapy

Complementary and prescription medicines can be used in an integrated manner to treat common ailments.

A Medical Journal of Australia Article, *Lipid Modifying Drugs* (21 March 2005) reports that the use of a statin in combination with fish oil is a relatively safe and effective option in treating high concentrations of triglycerides and/or LDL-C cholesterol.^{ix}

Switch and the Consumer

“Switch” refers to the transfer of prescription medicines proven to be safe and effective to over-the-counter status, improving accessibility to the consumer. In the United States, there are over 700 OTC products on the market using ingredients or dosages only available by prescription less than thirty years ago. ^x Uptake of these switched products can be very successful. Eleven “switched” brands in the United States generated US\$2.36 billion in annual sales and accounted for 55-60% of market growth. ^{xi}

As pharmaceutical products come off patent, and generic preparations enter the market, OTC switching of products is likely to occur as “branded” companies move to contain revenue loss. As a result of falling prices in generic prescription categories, pharmacy will probably begin to place greater attention on switched OTC preparations.

The idea that pharmaceuticals are only “switched” when proven safe after decades of distribution under prescription status is changing. ASMI believes that dose should be one of the primary factors when considering a switch. There are many applications such as statins in which a lower dose preparation is appropriate for OTC distribution while higher dosage preparations more appropriately remain prescription-only products.

In ensuring that safe and effective self-care products are available to Australians at reasonable cost, ASMI is committed to ensuring OTC and complementary products are used safely and effectively as they begin to play an increasing role in Australia’s overall health care strategy.

Benefits to Australians

The goal of an integrated self-care approach to health is ultimately to improve the lives of all Australians under a more sustainable and effective health system. Direct benefits to consumers include:

- Improved overall sense of health and ‘well-being’ and longer productive life expectancy
- Prevention of ill health
- Greater control over health decisions and as a result, greater confidence in the health system
- Lower private health insurance premiums due to reduced claims
- An improved health service as governments are able to divert funds saved from a reduction in demand on health care services to R&D, health support activity or reduced taxes
- Improved condition management, from minor ailments to chronic conditions
- Reduced time off work or out of role due to medical consultations

Statins – A Case for Switch

An estimated 14.8 million people worldwide use statins, a class of cholesterol-lowering drug aimed at reducing the risk of CHD accredited with saving over 17,000 lives annually. ^{xii}

In the past year the UK has allowed OTC status for a low dose statin, while the FDA and TGA are investigating the potential switch of certain substances in this class.

Coupled with strong consumer education and support, a switch of the substance to OTC status would provide a raft of benefits to Australians including ease of access and improved health outcomes.

Benefits to Health Care Services

Self-care can benefit the health care services in a number of ways. By 'sharing the burden', it allows all stakeholders to improve the effectiveness and efficiency of the services they provide. The direct benefits to health care providers would include:

- Reduced demand on overstretched government resources
- Fewer Medicare claims through a reduction in unnecessary GP visits
- Fewer admissions to hospital and out patient clinics
- Fewer accident and emergency visits

Savings in all these areas could allow Australia to invest more in the research and development of new medical technologies and techniques benefiting all Australians while supporting local industry.

Australian Success Story

The DHA report, *Returns on investment in public health* found that in regards to smoking prevention, publicly funded programs; ^{xiii}

- Have saved government \$344 million
- Or \$2 for every \$1 spent
- Male smokers down from 45% to 27% and females from 30% to 23%

Where to now?

- **Osteoporosis**
- **Cardiovascular disease**
- **Diabetes**

Types of Self-Care and Opportunity for Support

Caring for Minor Conditions

Minor ailments and injuries place a heavy burden on Australia's health care system. Many visits to the doctor are for minor conditions that could in many cases be treated just as effectively through self-care. Self-medication in consultation with

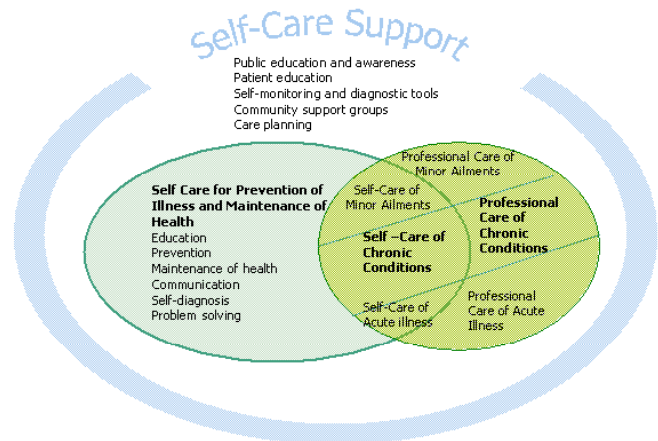


Figure 2: Self-Care and Self-Care Support

other health care professionals such as pharmacists would be appropriate in many cases. In any two-week period, 14% of Australians ^{xiv} will have one or more days off work due to illness, coming at a cost to the individual, employers and the government. Under a self-care paradigm, consumers would be more confident in treating and preventing many minor ailments themselves.

Australian consumers are ready for self-care. Research conducted by ASMI has shown that 90% of Australians would like to know as much as possible about any illness or condition they may have in order to improve their own self-care. 86% are confident in treating minor ailments themselves while 84% of individuals do what they can to self-care before visiting a doctor.

In treating minor ailments, 78% of Australians took self-care measures to manage their most recent condition.

Consumers are also responsible in purchasing OTC medicines. 94% of consumers describe themselves as very cautious and careful regarding the medications they take. 77% state they always read the label the first time they purchase an OTC product, primarily looking for dosage, any potential side effects, and ingredient information. ^{xv}

86% of GP consultations in Australia result in a prescription being written;^{xvi} it is thought that many of these could be treated with an over-the-counter or complementary medicine. Diverting some of the cost of medication to the consumer could result in significant savings in PBS expenditure (currently at \$6,001.2m)^{xvii}. The consumer would in turn save from reduced visits to the doctor and the associated costs involved such as transport and time off work.

- An NDMAC study found that by switching non-sedating antihistamines alone to OTC status, the Canadian government would save \$CD11.6m and the consumer, \$CD4.4m on doctor visits.^{xviii}
- Research conducted by the North-Western University (US) in 2004 found that over-the-counter medications used in treating common Upper Respiratory Infections (URI) potentially save the US economy \$US4.75 billion per annum in demand on health resources and lost productivity.^{xix}

Caring for Chronic Conditions

In the last National Health Survey, 87% of the Australian population was reported as having a long-term medical condition.^{xx} Chronic and long-term conditions pose a major obstacle to better Australian health:

- Chronic conditions are estimated to form 80% of the total burden of disease, mental illness and injury.^{xxi}
- 70% of GP consultations involved the treatment of a chronic condition of which the most common problem was non-gestational hypertension (9.2 per 100 encounters).^{xxii}
- 30.5 potentially preventable hospitalisations per 1000 population.^{xxiii} Chronic conditions account for the majority of bed days.
- As the Australian population ages, the prevalence of long term conditions will increase, further straining already stretched resources.

Self-care measures, such as life-style adjustments and self-medication, can both prevent and control chronic conditions. By identifying risk factors early, an individual can self-care by taking preventative actions and avoiding or delay the onset of a chronic condition. For people suffering from chronic conditions, self-care can be used to control the symptoms and manage complications.

Australians are interested in the prevention and management of illness, and are willing to look beyond the realm of conventional medicine for alternatives. In recent consumer research, 74% of Australians reported the use of at least one complementary medicine in the previous 12 months.^{xxiv} A South Australian study found that Australians spent \$2.3bn on alternative therapies in 2000, representing a 62% increase since 1993.^{xxv}

Information and ongoing support is required to provide the consumer with an understanding of their condition and the confidence to manage any symptoms or complications, and to slow down deterioration. Not only will this maintain a greater quality of life for the individual, but also it would reduce pressure on high cost services such as hospitals and aged care facilities by optimising the consumer's independent or productive lifetime.



Figure 3: Long term and chronic conditions, self-care/professional care breakdown.

Post Treatment Care

When a patient is discharged from hospital, self-care plays a primary role in ensuring rehabilitation. To prevent readmission or further deterioration, it is vital to ensure that patients understand their conditions and know where and whom to ask all the questions they may not have thought of when originally discharged.

For example, an elderly man required to recover for long periods in bed following treatment should be provided with simple exercises to maintain mobility in the upper body. He should also be provided with advice on medication to take to reduce the risk of thrombosis. This would help ensure the patient is able to resume his regular life post recovery and prevent further deterioration to a more dependent status.

Health care providers can supply important self-care advice and guidance through a rehabilitation program to ensure that normal function can be restored while maintaining a favourable quality of life.

Individual Measures to Ensure Adequate Self-Care

Individual Responsibilities

As self-care is an individual choice (see Figure 4), and since not everyone is in possession of the same skills or abilities, it is important to ensure that people have adequate access to the appropriate health care facilities and advice. Measures Australians can take for self-care include:

- Taking an interest in their own health and that of their family
- Following a healthy lifestyle
- Seeking out relevant health information when necessary
- Caring for minor illness
- Self-managing long term conditions with appropriate and relevant health care intervention and monitoring

- Collaborating with health care professionals such as doctors, and pharmacists with regards to the health of themselves and their family.

Required Skills and Knowledge

Self-care requires the individual to take greater control over his or her own health. Pre-requisite personal attributes to the effective and safe practice of self-care include:

- Adequate literacy and cognitive ability
- Existing knowledge
- Confidence
- A sense of efficacy
- Values and ethics
- Personal and community responsibility
- A desire to self-care.

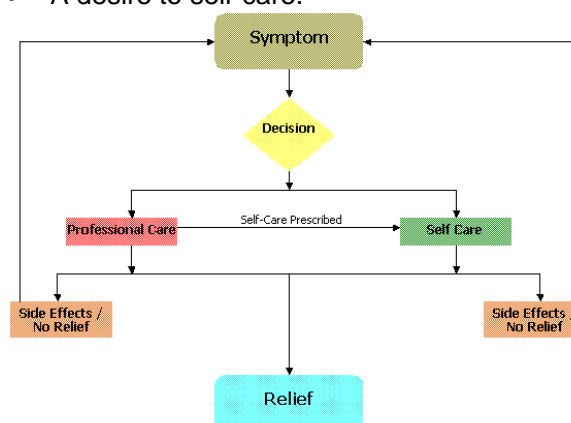


Figure 4: Consumer decision process

While governments and other bodies can play a vital role in providing the individual with the required skill set to self-care, it must be remembered that self-care is the consumer's choice.

Challenges

While the aim of self-care is to promote overall well-being and health in Australia, as with any health measure there are risks involved, including:

- Ensuring the individual meets the minimum requirements to be able to properly self-care

- Availability of resources to support the individual in making correct self-care decisions
- Equal opportunity of access to self-care
- Appropriateness of self-care measures chosen by the individual
- Ensuring open and effective collaboration between health care professionals and consumers

Governments and health care professionals can play a key role in ensuring Australians are equipped with the knowledge and skills required to safely and effectively self-care.

Supporting Self-Care

Current Initiatives

While not officially part of the Australian Government's health care strategy, there are a number of self-care related initiatives in place by both federal and state governments in addition to other relevant bodies. These include:

- The Active Australia program is the current federal umbrella health promotion strategy. It includes website and school curriculum requirements (www.healthyactive.gov.au).
- QUIT smoking campaigns and other condition/lifestyle specific campaigns (www.quit.org.au).
- Initiatives by GP groups to become more active in lifestyle intervention and promoting disease prevention.
- Pharmacy initiatives to promote self-care, such as self-care fact cards (www.psa.org.au).

The Role of Government

Government can play a vital role in ensuring a national environment conducive to consumers adopting self-care.

- Break through the 'silos' of individually funded and controlled health programs currently in operation to create a more

collaborative approach, as well as achieving greater efficiency and cost savings.

- Provide consistent and persistent public campaigns through mainstream media. The QUIT campaign is an excellent example.
- Provision in school curricula of material and activities to instil solid self-care values from an early age: physical education, medication safety, and general knowledge about the Australian health care system.
- Ensure that education continues in adulthood via public awareness campaigns and community health services.
- Establishment and maintenance of condition management groups and education resources for persons with chronic illnesses.
- Provision of tools and training to health care collaborators so that adequate self-care advice and support can be provided to the individual.

'The Government recognises that effective preventive action has the potential to make a great contribution to improving health outcomes and quality of life, minimising unnecessary demand for health care services, and ensuring these services are directed at those who really need them.'

The Hon Christopher Pyne MP, Parliamentary Secretary to the Minister for Health & Ageing speaking at the 2005 ASMI Conference.

- Provide incentives for industry in the self-care field, including implementing data protection periods to foster innovation in complementary and OTC medicines.
- Develop the health IT infrastructure and applications (such as the electronic health record) to enhance further the ability of doctors and pharmacists to provide self-care support.

- Encourage community participation in the formation of self-care strategies to ensure adoption.

Advocacy Groups

Advocacy groups play a vital role in Australian health. Generally representing a particular condition or range of related conditions, they form a powerful interface between the health user, the health system and its decision makers.

In addition to serving as a source of credible education for consumers, most groups strive to raise public and government awareness with regards to their condition and make the case for directing additional resources or education to assist people with a certain condition or to prevent the wider population from developing a condition.

Some important Australian advocacy groups include:

- Arthritis Australia
- Asthma Foundations of Australia
- Australian Injury Prevention Network
- beyondblue
- Cancer Council Australia
- Diabetes Australia
- Mental Health Council of Australia
- National Asthma Council Australia
- National Stroke Foundation
- Osteoporosis Australia
- The Heart Foundation

Self-Care Internationally

Several nations have already begun the move towards a broad approach to health and have built provisions for self-care and health promotion into their health policy.

- In 1994 the Canadian government officially endorsed the population health approach. This approach examines the health of populations or communities in achieving health outcomes. By directing investment at

root causes and promoting self-care, it aims to improve the health status of a population and reduce the need for heavy spending at the health care end of the spectrum.

- Following a breakthrough in 2000 in the NHS document *The NHS Plan*, self-care has received growing exposure and support in the UK. In late 2004 the Department of Health published the breakthrough communication entitled *Self Care – A Real Choice*, providing an introduction to the developing policy of self care support while providing a possible plan for the future. Committing to increasing the range of medicines available over-the-counter, the government has formulated a number of strategies aimed at improving Britain's health outcomes (see Image 1).

Health Wise Consumers

In a project beginning in 1996, Healthwise, a US based non-profit organisation, implemented the Healthwise Communities Project.

Distributed to 154,000 families and supported by a telephone advice service, the Healthwise Handbook contained 180 common ailments and information on how to self-care for them and when to consult a health professional. Support was provided to health professionals on working with a better-informed consumer.

A report into the success of the project found that the handbook saved an estimated US\$34.5m in fewer hospital visits during the 30-month campaign. This represented a saving of US\$11 for every US\$1 spent on the project.

Buoyed by the success of the project every family in British Columbia, Canada, has been provided with a handbook.^{xxvi}

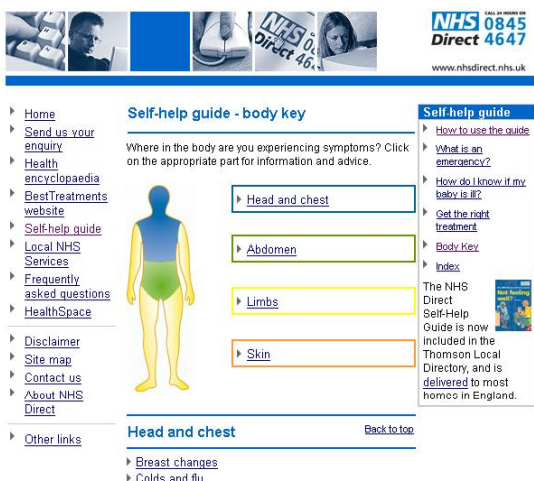


Image 1: NHS Direct, users can obtain self-care advice online or by phone by specifying their symptoms (www.nhsdirect.com).

Forging Solid Partnerships

ASMI believes that the success of self-care rests on the creation of strong partnerships amongst all the involved stakeholders. They include:

- Government
- Consumers
- Industry
- Educational Institutions
- Health Professionals/Collaborators
- Health Insurers
- Media.

Successful and meaningful cooperation and consultation between these groups is essential in ensuring that the common goal of improved and sustainable health outcomes for all Australians is achieved.

Self-Care: for All Australians

As Australia's health bill continues to swell under the challenges of technological advances matched by rising consumer expectations, demand for greater choice, and an ageing population, Australia must examine its health situation and provide health solutions that will benefit the whole community. In order to build a more sustainable and effective health system for

Australia, a comprehensive health policy is essential. By embracing the self-care model, Australians will be personally empowered to improve their own health outcomes and ensure Australia retains its place as a global leader in consumer health.

For more information about Self-Care visit us at <http://www.asmi.com.au/Self-Care.htm>.

ASMI Research

At ASMI's 2005 annual conference, the Parliamentary Secretary for Health, Christopher Pyne, announced that the Australian Federal Government will provide \$65,000 in funding to partner with ASMI in a research project to evaluate the evidence for selected complementary and OTC medicines. He told conference delegates:

"The Australian Government recognises that self-medication is an integral part of an Australian self-care system. In order to adequately respond to the needs of consumers, the Government depends greatly on the support of your industry to facilitate and encourage responsible and informed self-medication."

About ASMI

The Australian Self-Medication Industry is the peak industry body for the Australian self-care industry representing consumer healthcare products including over-the-counter medicines and complementary medicines. ASMI's mission is to promote better health through responsible self-care. This means ensuring that safe and effective self-care products are readily available to all Australians at a reasonable cost. ASMI works to encourage responsible use by consumers and an increasing role for cost-effective self-medication products as part of the broad national health strategy.

www.asmi.com.au

Appendix 1: National Health Priority Areas

Arthritis and Musculoskeletal conditions

Background:

- 2004-05 Health Survey estimates 15% of Australians suffer from arthritis
- 2004-05 ABS 40% of Australians living with Arthritis treat their condition with vitamins, minerals or herbal treatments. 37% used pharmaceutical medications.
- Estimated that 50% of Australian women aged 65 and over may have osteoporosis and not know it.
- The Australian Institute of Health and Welfare estimates that almost 75,000 years of healthy life are lost to arthritis annually.

Cost to government: \$4.6 billion (9.2% of total allocated health expenditure) ^{vii}

The Role of Self-Care

Diet
Exercise
Health Professional advice
Support & educational groups
Aspirin
Borage Oil (*Borago officinalis*) / gamma linolenic acid
Calcium / Vitamin D
Chondroitin
Devils Claw (*Harpagophytum procumbens*)
Diclofenac
Evening Primrose Oil / gamma linolenic acid
Fish Oil
Glucosamine
Ibuprofen
Naproxen
Nettle (*Urtica dioica*)
Paracetamol
Willow bark (*Salix spp*)

Asthma

Background:

- Effects 2 million Australians (10%), 1 in 4 primary school children
- 2004-05 ABS 3.1% of sufferers had one or more days out of work or study.
- Major cause of school absences, child emergency and hospital admission
- 60,000 Australians admitted annually
- Cost to employers for asthma-related absences in excess of \$110 million

COST: \$0.7 billion (1.7% of total allocated health expenditure) ^{vii}

The Role of Self-Care

Exercise
Health Professional advice
Support & educational groups
Inhalers (Preventers and relievers)
Nicotine Replacement Therapies (For smokers)
Non-sedating antihistamines

Cardiovascular Health

Background:

- Cardiovascular disease causes more deaths than any other disease, accounting for 50,797 deaths (40% of all deaths) in Australia in 1998.
- Coronary artery disease (mainly heart attacks) is the leading singular cardiovascular cause of death, accounting for 27,825 deaths (22% of all deaths) in Australia in 1998.
- Stroke is the major cause of serious long-term disability in adults.
- Most costly condition for the Australian health system. It was responsible for 12% (\$3.9 billion) of total recurrent health expenditure in 1993-94.

COST: \$5.5 billion (10.9% of total allocated health expenditure) ^{vii}

The Role of Self-Care

Diet
Exercise
Health Professional advice
Support & educational groups
Aspirin
Calcium
Co-Enzyme Q10
Folic Acid
Garlic
Ginkgo Biloba
Globe Artichoke Leaf (*Cynara scolymus*)
Nicotine Replacement Therapies (For smokers)
Omega-3 / Fish oils
Orlistat / Obesity medications
Psyllium / Ispaghula
Vitamins B, C & E - Multivitamins

Cancer

Background:

- Cancer currently accounts for 30.2% of male deaths and 25.2% of female deaths each year.
- Each year about 345,000 people are diagnosed with cancer. Approximately 270,000 of these are non-melanocytic skin cancers (the less threatening form of skin cancer).
- The most commonly detected cancers are prostate cancer in males, breast cancer in females.
- In 2006 there were 39,200 deaths in Australia from cancer, and the most common cancers causing death were lung cancer in males and breast cancer in females.
- At the prevailing cancer incidence rates, it may be expected that one in three men and one in four women could be directly affected by cancer by the age of 75.

COST: \$2.9 billion (5.8% of total allocated health expenditure) ^{vii}

The Role of Self-Care

Diet
Exercise
Health Professional advice
Support & educational groups
Nicotine Replacement Therapies (For smokers)
Saw Palmetto

Diabetes

Background:

- An estimated 940,000 Australians aged 25 years and over have diabetes; around half of these people are currently undiagnosed.
- The number of adults with diabetes has trebled since 1981
- Diabetes occurs in disproportionately high numbers in populations including
 - Older Australians
 - Aboriginal and Torres Strait Islanders
 - European born men and women
 - Asian born women

COST: \$0.8 billion (1.4% of total allocated health expenditure) ^{vii}

The Role of Self-Care

Diet
Exercise
Health Professional advice
Support & educational groups
Hydroxyethylrutosides (Chronic venous insufficiency)
Orlistat / Obesity medications
Vine Leaf (*vitis viniferae*) (Chronic venous insufficiency)

Injury Prevention

Background:

- Injuries result in an estimated 8,000 or 6% of deaths each year in Australia
- Approximately 400,000 hospital admissions annually are due to injuries
- Injuries are the main cause of death for people under the age of 45

COST: \$4.0 billion (8% of total allocated health expenditure) ^{vii}

The Role of Self-Care

Diet
Education
Exercise
Health Professional advice
Support & educational groups
Aspirin
Borage Oil (*Borago officinalis*) / gamma linolenic acid
Calcium / Vitamin D
Chondroitin
Devils Claw
(*Harpagophytumprocumbens*)
Diclofenac
Evening Primrose Oil / gamma linolenic acid
Fish Oil
Glucosamine
Ibuprofen
Naproxen
Nettle (*Urtica dioica*)
Paracetamol
Willow bark (*Salix spp*)

Mental Health

Background:

- About 1 in 5 Australian adults and 1 in 7 children will experience mental illness in any given year.
- The most common illnesses are anxiety, depression and alcohol dependence.
- In any one month, approximately 58,000 adults use psychiatric services due to psychotic illness. Schizophrenia accounts for around 40,000 of these.
- Of the approximately 500,000 children affected by mental illness, 200,000 have aggressive disorders, 93,000 with anxiety or depression, and 93,000 with attention disorders.

COST: \$3.7 billion (7.5% of total allocated health expenditure) ^{vii}

The Role of Self-Care

Diet

Exercise

Health Professional advice

Support & educational groups

Folate

Ginkgo biloba

Kava (*Piper methysticum*)

St Johns Wort (*Hypericum perforatum*)

Valerian (*Valeriana officinalis*)

Endnotes

- ⁱ Industry Estimate, 2004
- ⁱⁱ IBISWorld, Who are the real winners in Australia's war against the wobble?, (IBISWorld Press Releases, 2004), <http://www.ibisworld.com.au/static/PressReleases.asp?ContentItemID=184>
- ⁱⁱⁱ Australian Bureau of Statistics (ABS), National Health Survey 2004-05. (ABS, 2006)
- ^{iv} Australian Institute of Health and Welfare (AIHW), Health Expenditure Australia 2004-05. (AIHM, September 2006)
- ^v National Health Priority Action Council (NHPAC), Summary Report of the Aboriginal and Torres Strait Islander Health Workshop. (NHPAC, May 2003)
- ^{vi} Australian Institute of Health and Welfare (AIHW), Living Dangerously – Australians with multiple risk factors for cardiovascular disease (AIHW, February 2005)
- ^{vii} Australian Institute of Health and Welfare (AIHW), Health system expenditure on disease and injury in Australia, 2000-01 2nd Edition. (AIHW, April 2005)
- ^{viii} Pharmaceutical Society of Australia (PSA), Pharmacy Self-Care Research Report. (PSA, 2004)
- ^{ix} Leon A Simons and David R Sullivan, Lipid Modifying Drugs, 2005; 182 (6):286-289 "The Medical Journal of Australia"
- ^x Consumer Healthcare Products Association (CHPA), OTC Facts and Figures, (CHPA 2005), http://www.chpa-info.org/web/press_room/statistics/otc_facts_figures.aspx
- ^{xi} Alain Bonta, How to get your brand to the consumer, presentation to the Association of the European Self-Medication Industry (AESGP) May 2000.
- ^{xii} Pharmaceutical Field, Statins go OTC in Britain. (Pharmaceutical Field 2005) <http://www.pharmafield.co.uk/asp/article.asp?id=114&source=1>
- ^{xiii} Department of Health and Ageing (DHA), Returns on Investment in Public Health : An epidemiological and economic analysis. (prepared for the DHA, September 2004)
- ^{xiv} Australian Bureau of Statistics (ABS), National Health Survey 2001. (ABS, 2002)
- ^{xv} Dr David N Darby, The Consumer's Perspective on Health and Medication with an emphasis on self-care and self-medication. (Australian Self-Medication Industry, 1996)
- ^{xvi} Australian Institute of Health and Welfare, University of Sydney, General Practice Activity in Australia 2003-04. (AIHW, December 2004)
- ^{xvii} Pharmaceutical Benefits Pricing Authority, Annual Report for the year ended 30 June 2005. (DHA, Dec 2005)
- ^{xviii} Nonprescription Drug Manufacturers of Canada, The Economics of Self-Medication. (NDMAC, 30 June 1995) <http://www.ndmac.ca/>
- ^{xix} NorthWestern University Media Relations, Over-the-counter Drugs Could Save \$4.75 Billion Annually. Media Release. (NorthWestern University, 9 November 2004)
- ^{xx} Australian Bureau of Statistics (ABS), National Health Survey 2001. (ABS, 2002)
- ^{xxi} Australian Institute of Health and Welfare, Health system expenditure on chronic diseases. (AIHW, 23 June 2005)
- ^{xxii} Australian Institute of Health and Welfare, University of Sydney, General Practice Activity in Australia 2003-04. (AIHW, December 2004)
- ^{xxiii} Australian Institute of Health and Welfare, Australian Hospital Statistics 2003-04. (AIHW, 27 May 2005)
- ^{xxiv} Cardinal Health, Vitamin, Mineral, Herbal and Nutritional Supplements (Cardinal Health, 2004)
- ^{xxv} Ian D Coulter and Evan M Willis' The rise and rise of complementary and alternate medicine: a sociological perspective. MJA 2004; 180 (11): 587-589 (Medical Journal of Australia, 2004)
- ^{xxvi} Healthwise, Partners health initiative estimates \$34.5 million savings in unnecessary health care costs. (Healthwise, 2004)



Document Revised July 2007



AUSTRALIAN SELF-MEDICATION INDUSTRY
BETTER HEALTH THROUGH RESPONSIBLE SELF-CARE

Australian Self-Medication Industry Inc

ABN 55 082 798 952

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

info@asmi.com.au www.asmi.com.au