



# **Increasing Access to Medicines to Enhance Self Care**

**Position Paper - October 2009**

## Executive summary

The Australian healthcare system is currently at a crossroads, with the government contemplating significant reforms to address ballooning healthcare budgets and issues associated with chronic disease.

A number of recent government inquiries have identified pathways for reform, with a notable emphasis on a more patient-centred approach to primary care, encompassing greater personal responsibility and a focus on preventative health.

This approach is closely aligned with ASMI's policy of self care – centred on enhanced personal responsibility for minor ailments and chronic conditions in partnership with a healthcare professional such as a doctor or pharmacist.

For self care to reach its full potential, as is occurring in the UK health system, there needs to be a number of associated changes to the way people look after their health – such things as improved health literacy and public information, as well as providing pharmacists and other health professionals with the tools to perform some of the tasks currently undertaken by GPs.

There also needs to be some fresh thinking in regard to the regulation of medicines, to enable consumers to have easy and affordable access to medicines and treatments for some of the most common health conditions.

Inevitably, this means consideration to rescheduling some prescription medicines that have proven safe and effective over a long period of time so that they are available over-the-counter through pharmacy.

The wider availability of safe, proven and affordable medicines has the potential to make a profound impact on public health. It opens the way for consumers to better play their part in the self care environment through access to information and therapeutic products to treat illness and maintain good health.

Not only is this beneficial to the consumer, but it helps to make better use of the clinical skills of pharmacists, empowering them to play an active role in the management of primary health, particularly minor ailments and chronic conditions. For this to occur there will need to be some key foundational steps. These include:

- Clear government policy and involvement from all stakeholders;
- An agreed list of disease categories to target;
- Consumers willing to empower themselves with information;
- Access to information for consumers and healthcare professionals;
- Healthcare professionals with the skills and tools to manage chronic and more serious conditions in collaboration with GPs; and
- Regulatory processes that facilitate the rescheduling of medicines without compromising public health and safety

ASMI believes a proactive approach to increasing access to medicines and providing the tools and information for consumers to engage in self care has the potential to deliver significant public health, social and economic benefits.

Accordingly, ASMI proposes a partnership approach between the key stakeholders aimed at making increased access to medicines a fundamental plank of the emerging health policy landscape.

## Self care

Self care encompasses a broad spectrum of decisions and activities undertaken by individuals and the wider community in order to improve health, prevent disease and manage illness. Self care may be undertaken alone (like treating a headache) or may occur in collaboration with a healthcare professional. In that sense, self care encompasses a partnership between the individual and a healthcare professional such as a doctor or pharmacist.

The collaboration between the individual and the healthcare professional (such as the doctor or pharmacist) is pivotal to providing an environment conducive to self care. It involves equipping consumers and healthcare professionals with the options, skills and tools necessary to maintain health or manage medical conditions.

The benefits resulting from the promotion of self care include:

- 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;
- better use of scarce healthcare resources through an expanded role for pharmacists and more appropriate use of GP and hospital services.<sup>1</sup>

Fundamental to the success of self care is the formation of strong partnerships between stakeholders. Self care does not mean consumers are left on their own; nor does it translate into "no care". It requires informed consumers; the expertise of pharmacists, GPs and other practitioners; provision by industry of evidence based medicines; the creation by government of a favourable policy and regulatory environment; and innovative approaches from private health insurers.

## Increasing access to medicines

The wider availability of safe, proven and affordable medicines has the potential to make a positive impact on public health by providing consumers with easier, more convenient and faster access to therapeutic products to treat illness and maintain good health. The burden being experienced by GPs can also be addressed by making better use of the clinical skills of pharmacists and empowering them to play an active role in the management of primary health, particularly minor ailments and some chronic conditions.

## Key considerations

- Consumer expectations – autonomy, choice and convenience
- The burden of disease
- Making optimal use of healthcare resources
- The need for clear government policy
- The need for high quality information and education
- Identifying areas and indications for increasing access to medicines
- Regulatory processes that would facilitate increased access to medicines

## Consumer expectations

Consumers want to be more actively involved in the management their own health and are increasingly taking greater control of their own healthcare. As they are becoming more informed, better educated and, consequently, better equipped to take more responsibility for maintaining health and managing medical conditions, they are becoming more demanding and proactive in their choices.<sup>2</sup>

This desire to take more responsibility for personal health is an important dynamic behind the increasing trend toward the use of medicines which are available without prescription.

People also expect to have a range of choices of effective medicines and ready access to those medicines. Increasing access to medicines improves choice and empowers consumers to take more control of their own healthcare.<sup>3</sup>

## The burden of disease

Currently, eight different health areas have been identified for priority attention as Health Priority Areas (HPA): arthritis and musculoskeletal conditions; asthma; cancer control; cardiovascular health; diabetes mellitus; injury prevention and control; mental health; and obesity.

Taken together, the eight HPAs account for almost 80 per cent of the total burden of disease and injury in Australia.<sup>4</sup> Increasing access to medicines used in the prevention and treatment of conditions in five of these areas has the potential to make a significant impact on the burden of disease and public healthcare expenditure.

These are:

- arthritis and musculoskeletal conditions
- asthma
- cardiovascular health
- diabetes mellitus
- obesity

Arthritis and musculoskeletal conditions were estimated to account for 4 per cent of the disease burden in Australia in 1996, in terms of disability-adjusted life years (DALYs). In monetary terms, the direct costs of arthritis and musculoskeletal conditions were estimated at \$4.7 billion in 2000-01.<sup>4</sup>

Asthma was estimated to account for 3 per cent of the disease burden in Australia in 1996, 1 per cent of years of life lost due to premature mortality and 5 per cent of years of 'healthy' life lost due to poor health or disability. In monetary terms, the direct costs of asthma were estimated at \$615 million in 2000-01.<sup>4</sup>

Cardiovascular disease is the largest cause of premature death in Australia. Although death rates for cardiovascular disease have declined considerably in recent decades, it continues to be one of the biggest health problems requiring attention in Australia. Its health and economic burden continues to exceed that of any other disease.

Cardiovascular disease was responsible for almost 22 per cent of the burden of disease in terms of disability-adjusted life years in Australia in 1996. In monetary terms, the direct costs of cardiovascular disease were estimated at almost \$5.4 billion in 2000-01.<sup>4</sup>

Diabetes mellitus was responsible for just under 5 per cent of the burden of disease in disability-adjusted life years in Australia in 1996. In monetary terms, the direct costs of diabetes mellitus and its complications were estimated at \$836 million in 2000-01 and this is expected to increase as the population ages.<sup>4</sup>

Obesity can cause a range of health problems, and adds to Australia's Health Costs significantly. High body weight was thought to be responsible for 7.6% of the total burden of disease in 2003, coming just after tobacco and high blood pressure. Access Economics (2006) estimated that in 2005 the total financial cost of obesity in Australia was \$4 billion.<sup>4</sup>

## Making optimal use of healthcare resources

### *Expanding the role of pharmacists in primary healthcare delivery*

Consumers will need to have access to appropriate professional support and advice in order to properly look after themselves and their families. Pharmacists are ideally placed in the community to provide this support as well as quality information to assist consumers in making informed choices and better manage their own health.<sup>5</sup>

Pharmacists already make a significant contribution to health improvement through services such as smoking cessation and weight management. As part of the drive towards greater self care, the professional role of pharmacists needs to be expanded to include involvement in the treatment of conditions traditionally seen as the preserve of the prescriber.<sup>3</sup>

To make the very best use of the potential offered by pharmacists, they would need to have access to the 'tools' to do the job, which include access to medicines. It may be possible that after initial diagnosis and prescription, the GP can delegate control to the pharmacist for further management, including medication management, while retaining an advisory role such as in the case of diabetes and asthma.

### *The role of General Practitioners*

The active participation of General Practitioners in the shift towards more self care is crucial. The opportunities for supporting self care are particularly significant in general practice as GPs are the most visited health professional, with about 85 per cent of the population seeing a GP at least once a year.<sup>6</sup> In addition to their primary role as diagnostician and prescriber, they have an important role as an educator and endorser of a change in behaviour among individuals as well as other healthcare professionals.

The current clinical workload of GPs requires close scrutiny to determine whether their skills and expertise are used optimally. In her "Light on the Hill" speech the Federal Minister for Health and Ageing, Nicola Roxon said: "*With doctors weighed down by the urgent needs of acute care, as well as unnecessary administration, we need to consider how we can unburden them of some of this work where it is safe to do so...*"

By making better use of the skills of pharmacists in the management of not only minor ailments but also stable and chronic conditions, valuable GP resources can be redirected towards the management of serious and acute conditions.

## The need for clear government policy

Clear government policy direction supported by all stakeholders is essential to give impetus to the drive towards greater self care. The Australian government has recognised the need for change and has embarked on a range of initiatives aimed at setting new policy direction.

The National Health and Hospitals Reform Commission (NHHRC) is one such initiative. In its report the Commission states: *“There is not sufficient recognition of our own capacity to take action and improve our own health, supported by our families and communities. We heard about the vital importance of recognising and nurturing self-management to support people to take greater control in managing their health issues”*.

It goes on to make, amongst other, the following recommendation:

*“We support strategies that help people take greater personal responsibility for improving their health through policies that ‘make healthy choices easy choices’. This includes individual and collective action to improve health by people, families, communities, health professionals, health insurers, employers and governments”*.

It would be useful to also consider relevant international experience where self care has been formally incorporated into health policy. The UK is widely considered to be leading the way in promoting self care and is at the forefront of innovative self care indications. It is NHS policy to empower patients and optimise the roles and contribution of healthcare professionals in delivering patient care.

The UK government is committed to making more medicines more widely available through rescheduling when it is safe to do so and is keen to move the agenda to encompass not just acute, short term, self-limiting conditions but also new areas of chronic disease management.<sup>3</sup>

The All Party Parliamentary Group (APPG) on Primary Care and Public Health inquiry concluded: *“We acknowledge the positive impact more convenient and faster access to non-prescription medicines has on primary care and public health. We recommend that the MHRA continues to widen access to OTC medicines in close collaboration with its stakeholders”*.<sup>3</sup>

In Australia healthcare professionals and people involved in healthcare delivery are also the focus of new policy developments. Recommendation Number 98 in the NHHRC report states:

*“We recommend supporting our health workforce by:*

- *promoting a culture of mutual respect and patient focus of all health professions through shared values, management structures, compensation arrangements, shared educational experiences and clinical governance processes that support team approaches to care”*.<sup>7</sup>

Launching the Pharmacy Guild’s 2009 “Ask Your Pharmacist” week, Federal Health Minister Nicola Roxon acknowledged the important role pharmacists play in healthcare delivery:

*“.....pharmacists are ideally placed in the front line of health service provision to form part of a multi-disciplinary team that delivers the services and resources most relevant to the needs of the community. This will help achieve our aim of focussing resources on what is best for the patient – better outcomes, a reduction in inequalities and a better journey through the health system.”*

Again turning our attention to the UK - in its White Paper, *Pharmacy in England – Building on strengths – delivering the future*, the UK government sets out a vision for building pharmacy.<sup>5</sup> It is the UK government’s conviction that pharmacists are a significant untapped resource for delivering accessible services to consumers and it is looking to the profession to develop leadership to support and sustain pharmacy, including opportunities to become prescribers.

The proposed improvements include better access to pharmacists' expertise on medicines, expanding the range of medicines available without prescription to treat the conditions that pharmacists can be involved in and supporting people with long term conditions (e.g. diabetes and asthma).

The Australian government's initiatives present huge opportunities for change and the focus on increased personal responsibility for health and wellbeing, and the role of individuals, communities, health professionals, employers and governments is encouraging. What needs to happen now is to develop and implement formal policies which will bring about this reform.

## The need for high quality information and education

Increased access to medicines must be accompanied by appropriate measures to ensure safe use of the medicines. Giving consumers more choice and responsibility must also involve ensuring that they are equipped to make sensible choices. The strengthening of information and education is a critical element in achieving this objective.<sup>8</sup>

Clear strategies need to be developed to raise the knowledge amongst consumers to a level necessary to enable them to assume more responsibility in the management of the medical condition, including the point at which a return to the healthcare professionals for advice and/or intervention is necessary.

Pharmacists have a key role to play in providing assistance, advice and information to consumers about medication and the circumstances in which a doctor or other healthcare professional should be consulted. To help them perform this role they will require specially-tailored information material and appropriate training.<sup>8</sup>

Industry is well placed to provide high quality information about medicines as well as training and education where the expanding pharmacy role would include advice and consultation on more serious and chronic conditions being treated. Official or accepted evidence-based consensus guidelines or an agreed approach for assessing expert opinions concerning the management of the medical conditions need to form part of a comprehensive information package.

## Identifying areas and indications for increasing access to medicines

A useful starting point for discussion would be to consider work that has already been done in this area.

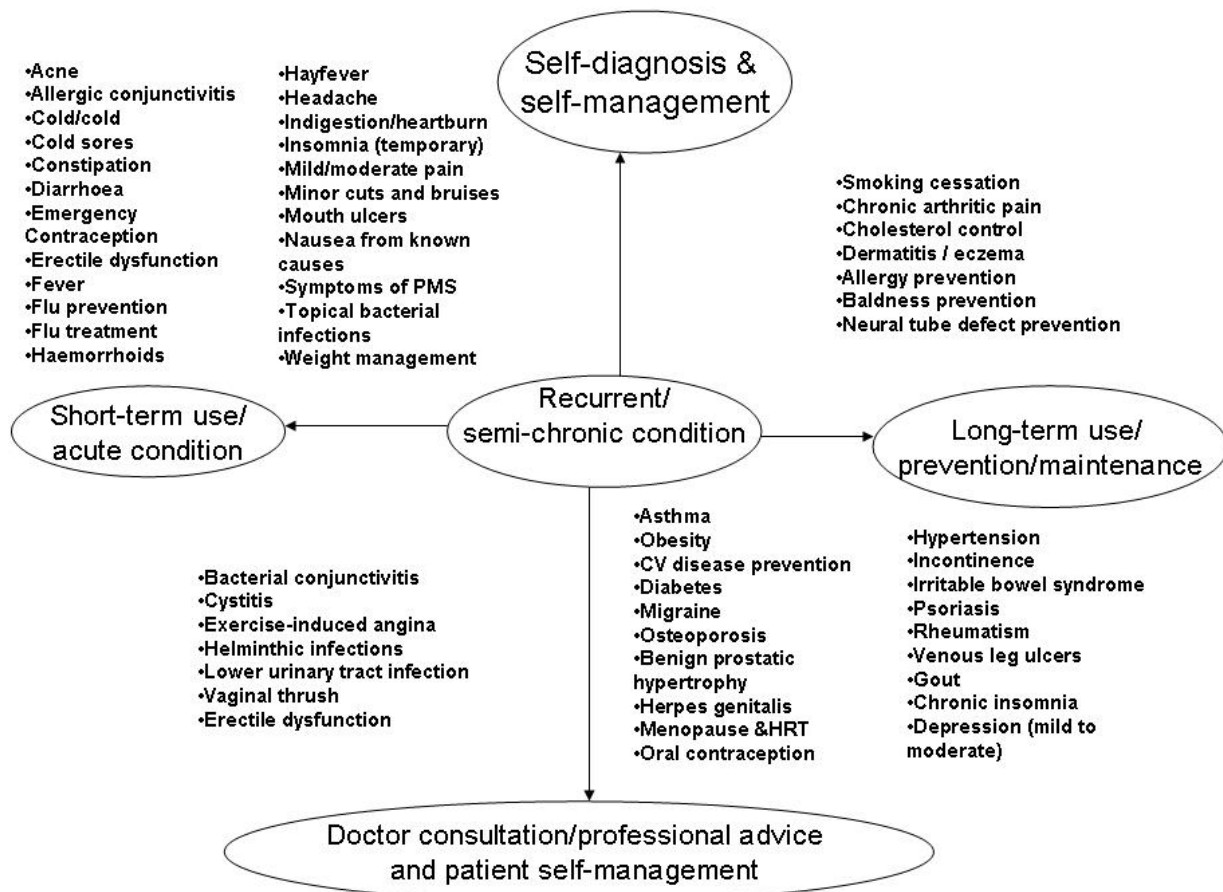
In 2002 the AESGP Foundation published a report on a research project, "Development of an information policy for medicinal products".<sup>8</sup> The main objective of the research, which was supported by the European Commission, was to examine the information needs of both the public and healthcare professionals in case the range of conditions that can be treated with non-prescription medicines were to be extended to categories currently not available without prescription by a medical practitioner.

A dedicated Task Force examined how a possible expanded role for self-medication could be achieved and established a suitable way of describing indications currently available without prescription together with indications or conditions that might be considered for making medicines available without prescription.

The chart below maps indications according to the following criteria:

- Is it an acute condition requiring short-term use of a medicine; is it a semi-chronic condition requiring recurrent use of a medicine or is it a chronic condition requiring long-term use of a medicine?
- Is it a condition that can easily be self-diagnosed and self-managed or is it a condition that requires prior consultation of and diagnosis by a medical doctor?

Self care indications chart (adapted from AESGP)



For indications in the top half of the chart, i.e. the traditional self-medication area, the following questions are usually asked to determine whether these indications are suitable for self-treatment:

- Can the condition be easily self-diagnosed?
- Is the illness self-limiting?
- What underlying conditions might be masked by self-treatment?
- Does the product have a wide safety margin?
- Can the product be used safely without medical supervision?
- Will the use of the product lead to misuse, abuse or dependence?
- Will the product present a hazard to the community if used unsupervised?
- Can consumers comprehend the label and understand the warnings?

The conditions in the bottom left-hand quadrant are gradually becoming available without prescription in certain countries. Once the doctor has established the medical diagnosis, consumers can recognise the condition when it recurs and treat it with a non-prescription medicine. The pharmacist can, in this collaborative care setting, provide valuable information and advice on treatment options and when to consult the doctor again.

The bottom right-hand quadrant included the conditions identified as possible new candidates for treatment in this collaborative care setting. The Task Force identified the following additional questions to determine if these indications would be suitable for self-treatment:

- Is the illness life threatening?
- Can the management of the condition/disease be enhanced by greater access to products available without prescription?
- Can the pharmacist assist in the management of the disease?
- Can patients adequately self-monitor (through the use of a device) and self-treat asymptomatic diseases?
- Is the illness stable over the recommended treatment period?
- Is the treatment regimen simple and easy to follow or does it require dose titration?
- What is acceptable compliance/non-compliance for treatment of the disease/condition?

ASMI believes the following areas should be considered for increasing access to medicines:

- Cholesterol control
- Obesity
- Asthma
- Diabetes
- Migraine
- Oral contraceptives

## Regulatory processes need to facilitate increased access to medicines

Once government policy to expand self care and to increase access to medicines has been established, steps need to be taken to ensure that the regulatory environment supports the new policy directions. There is already agreement to implement a new framework for the scheduling of medicines in Australia and this presents an ideal opportunity to review all aspects of the framework, including scheduling criteria, administrative processes and advertising arrangements to ensure that the regulatory framework will facilitate more medicines becoming available more widely.

## Conclusion

We believe that an environment conducive to increasing access to medicines would be characterised by the following:

- Clear government policy and buy-in from all stakeholders;
- Agreement on the disease categories to be targeted for increasing access to medicines, based on the current burden of disease and where the greatest impact on public health could be achieved;
- Consumers who are empowered to make informed decisions about their healthcare;
- Ready access to information to assist consumers and healthcare professionals to make appropriate healthcare decisions;
- Healthcare professionals who have the skills and tools to accept greater responsibility for managing chronic and more serious conditions in collaboration with GPs; and
- Regulatory processes which would facilitate rescheduling of medicines without compromising public health and safety

ASMI advocates a proactive approach to increasing access to medicines as an integral part of the drive towards greater self care. We call for a partnership approach to provide impetus to this drive – working with all stakeholders to create an environment that would facilitate an increase in access to medicines that would deliver public health, social and economic benefits for all.

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