Dear Sir or Madam,

Re: ASMI Response to the Review of Pharmacy Remuneration and Regulation, July 2016

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

ASMI is committed to expanding and promoting Quality Use of Medicines (QUM), which is central to the National Medicines Policy. The goal of QUM is to make the best possible use of medicines by:

- Selecting management options wisely
- Choosing suitable medicines if a medicine is considered necessary
- Using medicines safely and effectively.

Mechanisms and initiatives supported by ASMI that contribute to QUM include:

- Provision of information and education, in partnership with other key stakeholders
- Setting standards for promotional activities via the ASMI Code of Practice and participation in the co-regulatory arrangements for promotion of OTC medicines

ASMI appreciates the opportunity to provide comment in relation to some of the questions raised in the Discussion Paper.

As an industry representative, ASMI is keen to provide further input as required.

Please contact me should you require any further clarification relating to this submission.

Yours sincerely,

Quality Use of Medicines Manager

Advancing consumer health through responsible self care
**Question 25. As medicine specialists, what are the professional programs and services that pharmacists should or could be providing to consumers in order to best serve the consumers?**

Healthcare resources in Australia are scarce and all sectors agree that they should be used rationally and effectively to achieve best health outcomes with best value for money for individuals and for the community as a whole.

Pharmacists are ideally positioned to provide population health support services to consumers. Some of these services are already in place, e.g. influenza vaccinations, weight loss management and smoking cessation. However, we believe there is scope for expanding primary healthcare services into other areas, e.g. the management of common minor ailments.

The standards of delivery of these programs vary widely in quality and content between pharmacies across Australia. The opportunity is for Government to work with Pharmacy to identify and accredit evidence-based population health intervention strategies and potentially remunerate pharmacists for delivering these programs, provided the appropriate accreditation was obtained by the pharmacist providing the service.

It is generally acknowledged that general practitioners are overstretched and ideally need more time to dedicate to consumers with one or more chronic diseases and to the management of acute illness. A study by IMS in 2009\(^1\) demonstrated that between 7% and 15% of visits to general practitioners are for minor ailments. If this time were made available to general practitioners, benefits would include better use of both doctor and pharmacy resources and could include improved satisfaction for consumers with respect to travel and waiting times.

In this instance “minor ailments” were defined as self-limiting conditions where the management is the same through general practice, pharmacy or self-care and includes conditions such as, but not limited to, conditions such as common colds, strains and sprains, acute diarrhoea, constipation, muscle aches and pains, allergies, headache, rash, dermatitis and eczema, fevers, foot conditions such as corns and callouses and others.

ASMI believes that further research should be conducted with a view to developing and testing models of professional programs and services, such as minor ailment schemes, that can deliver benefits to consumers and also expand provision of services to the community by pharmacists.

**Question 26. Should there be limitations on some of the retail products that community pharmacies are allowed to sell? For instance, is it confusing for patients if non-evidence based therapies are sold alongside prescription medicines?**

It remains appropriate for healthcare products to be sold in pharmacy, regardless of the levels of evidence. However, accurate and balanced information, i.e. the level of existing evidence about products sold in pharmacy should be available to consumers to support informed decision-making.

There are, for example, many “grandfathered” medicines which have a very long history of safe use, but the evidence supporting those products would not necessarily meet contemporary standards of evidence. Because there is little or no modern clinical data supporting their efficacy these would be considered “non-evidence based therapies”. Empirical usage and low incidence of side effects support their ongoing availability. In addition, pharmacy customers will always have the opportunity of acquiring information about the product they are interested in purchasing and could be redirected to more appropriate products should the one they are enquiring about be inappropriate.

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1 ASMI Minor Ailment Report 2009 (David Gadiel)
**Question 31. If an MBS payment for professional pharmacy advice was introduced, what level of service should be provided? Should the level of payment be linked to the complexity of particular medicines? Should it be linked to particular patient groups with higher health needs?**

There are considerable opportunities for development of pharmacy “minor ailments” or “triaging” schemes as well as accredited population health interventions such as weight loss, vaccinations, smoking cessation and others.

Minor ailment schemes, and the population health interventions described above are good examples of enhanced pharmacist primary care. There is no reason why GPs should provide the only gateway to primary care and further research into alternative care models should be considered.

Further research could also inform future considerations of the levels of payment that could be linked to particular services. An MBS payment could, for example, be linked to accredited population health interventions including but not limited to programmes such as smoking cessation, vaccination, and weight loss.

Limiting payment only to those with higher health needs or on complex medication regimens may negate the potential long-term benefits of these interventions to the wider population.

**Question 38. If particular health services were deemed to be of clinical value and delivered good patient outcomes, what other mechanisms could allow these programs to be disseminated around the country to relevant communities and groups on an affordable basis?**

Consideration should be given to individual independent pharmacists not connected to a pharmacy premises or business, who could provide affordable, professional health services.

**Question 110. How informed are consumers of the scope of medicines and related services that can be provided by pharmacists without referral to a General Practitioner?**

There is very limited promotion of pharmacy services in consumer media, mostly due to regulation and cost. Consumers who come into contact with pharmacy through the use of prescription medicines would become exposed to pharmacy services but they are more likely to have a specific need.

In general, most consumers are unlikely to be aware of or have specific knowledge of what services community pharmacy offer. In many cases this may lead to utilising GP services when engaging with a pharmacist would have been a more efficient, cost-effective action. There are also tangible benefits that include more efficient use of GP time and expertise and allowing GP redeployment to areas of national priority, such as the management of chronic disease that will become an increasing priority with Australia’s ageing population.

Development and implementation of pharmacy minor ailment or enhanced care programs will improve pharmacy links with the rest of the primary care sector. The introduction of such a model will require pharmacist and pharmacy assistant training and accreditation, retail formats that are conducive to individual and more private interaction between consumers and pharmacists, as well as GP education.

A consumer education and engagement strategy will also be needed to drive cultural change and educate consumers and other stakeholders on the expanded role of pharmacists in delivery of health services.
Question 111. To what degree do current advertising restrictions limit the ability of pharmacies to promote medicines and related services available to consumers?

The current advertising restrictions on schedule 3 medicines are unjustified because they deliver no net public health benefit. In fact, the restrictions have a negative impact. They constrain the ability to make consumers aware of treatments which are available without a prescription. Consequently, consumers continue to consult GPs for conditions which could be safely managed by pharmacists.

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 conditions and maintain good health.

The current arrangements disempower consumers because “they are not allowed to know” about these medicines. It is difficult to mount a public health benefit argument to support these restrictions, especially in view of the mandatory involvement of a leaned intermediary in the supply of these products.

ASMI has put forward an alternative regulatory model for raising consumer awareness of S3 medicines. The ASMI model would permit direct to consumer communication on S3 medicines as a default, with a process that also recognises the categories of S3 medicines that should not be advertised, such as medicines that have abuse potential or those that require close medical supervision (for example codeine containing analgesics and products containing pseudoephedrine). The model also provides for a structured and standardised framework for communicating information in a balanced manner. The goals are to create disease awareness, emphasise the critical role of the pharmacist and create product awareness. Public health and safety will be maintained through existing advertising controls which are robust and comprehensive.

ASMI also acknowledges the benefit of promoting health related services provided by pharmacy through advertising, particularly if it encourages more health conversations and health checks. Consumer engagement and awareness are key aspects of the development of future pharmacy practice models that deliver health services to the community.

Question 112. In your experience, do community pharmacists provide appropriate advice for Schedule 2 and 3 medicines?

ASMI believes that community pharmacists do provide appropriate advice for consumers in the supply of S2 and S3 medicines. Research conducted by ASMI on consumers’ use and attitudes toward OTC (over-the-counter) medicines\(^2\) provides some important insights into the importance of these medicines to consumers and their impact on well-being.

This research showed that 83% of consumers surveyed had used more than one OTC medicine in the past month, with cough and cold medicines, analgesics, digestive health products, allergy / sinus products being commonly used S2 and S3 medicines. Of these purchases, 77% were from the pharmacy – either front of counter or behind the counter. More than half of consumers surveyed indicated that if they were unable to obtain their OTC medicine from the pharmacy, they would visit their doctor. This would have a significant impact on health care costs and productivity and it would adversely impact on the availability of overstretched GPs.

Consumers were asked about their general attitude toward OTC medicines, and were asked to either agree or disagree with certain statements (using ranked responses). Although OTC medicines include both scheduled and unscheduled medicines, ASMI believes that the results indicated that consumers are in

\(^2\) Macquarie University Consumer Factbook, March 2015
general very satisfied with the information and service provided by pharmacists and pharmacy staff, with the following notable findings:

- 73.5% of consumers surveyed agreed with the statement “Pharmacist recommendations help me make the best choices”
- 72.8% of consumers surveyed agreed with the statement “I usually follow the advice I’m given in the pharmacy”
- 68.9% of consumers agreed that “Choosing the right OTC medicine is extremely important to me” – thus highlighting the importance of advice to the consumer

Other significant findings of this research include that consumers want to know more about their OTC medicines and that the convenience of access to these medicines without a prescription is important to them.

The current advertising restrictions on schedule 3 medicines constrain the ability to make consumers aware of treatments they can request without a prescription. Consequently, consumers do not know to ask for these schedule 3 medicines as they are unaware they exist. The schedule 3 category is undeveloped in Australia as a result. Typically the consumer comes in and is triaged by the pharmacy assistant as the first port of call for over the counter and complementary medicine needs (Schedule 2 and unscheduled products). They are usually referred to the pharmacist only if the request is complex and/or if a schedule 3 medicine is a more appropriate option.

Pharmacists are uniquely positioned to optimise health outcomes for consumers through their accessibility, continuing training and professional practice standards. The PSA’s Standards for the Provision of Pharmacy Medicines and Pharmacist Only Medicines\(^3\) sets the standards for pharmacists’ professional obligations in relation to S2 and S3 medicines.

ASMI supports the current arrangements with the addition of advertising of Schedule 3 medicines, and believes that pharmacists are well placed to play an expanded role in the delivery of healthcare services and supports the enhanced role of the pharmacist in delivery of primary care.

**Question 113. Are the current restrictions on the sale of Schedule 2 and 3 medicines an appropriate balance between access and health and safety for consumers? If not, how could this balance be improved?**

ASMI believes that the current arrangements for consumer access to medicines is appropriate and should remain unchanged. Of the various access options that may be seen globally, ASMI believes that the Australian model provides a good balance that enables availability of advice, ease of access, affordability for consumers, as well as mitigation of risk to enable consumer safety.

Pharmacists are highly trained and operate within a legal framework that specifies various controls on public access to scheduled medicines, commensurate with risk. ASMI believes that consumers should be able to self-select S2 medicines and that states and territory legislation should be harmonised to permit self-selection in all jurisdictions. This would be consistent with the principles which differentiate S2 and S3 i.e. S2 restricted to sale in a pharmacy where advice is available if required and S3, which requires mandatory intervention by a pharmacist.

The S3 schedule also provides a more controlled environment for consumers to access medicines which have been “switched” from prescription only, which if utilised more effectively can drive innovation in the delivery of medicines to consumers in a much more cost-effective way without adversely affecting

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consumer safety. Switching of medicines to S3 can also provide benefits by reducing pressure on GPs who are seeing some patients who can be easily assessed and appropriately treated by pharmacists. ASMI therefore believes that the current framework and restrictions for supply of S2 and S3 medicines are in the interests of consumer safety, allow convenient access and have the potential to drive innovation in delivery of consumer healthcare.

**Question 114. Is the sale of schedule 2 and 3 medicines an important contributor to the income of community pharmacies?**

Non-prescription medicines are an important and growing part of pharmacy and the pharmacy offering to the health consumer.

As per the chart below, unscheduled, S2 and S3 (total non-prescription medicines) make up 26.4% of total Pharmacy sales.

![Growth of the OTC market vs. Total market](image)

*Source: IMS National Audits (API+AHI) – ex-wholesaler list price – MAT December 2015*

Access to Schedule 2 and 3 medicines in the pharmacy environment offers important benefits to the consumer and to the health system, providing easy and affordable access to advice and consumer requests for information as well as effective products that relieve minor ailments and self-limiting conditions without the need to visit a GP. The economic benefits of non-prescription medicines to the health system are well recognised – saving unnecessary visits to doctors, savings to the PBS in an appropriate and risk averse manner.

**Question 115. Does the availability and promotion of vitamins and complementary medicines in community pharmacies influence consumer buying habits?**

At least 70%⁴ of Australians use complementary medicines, with usage strong across all age, gender, education and socio-economic groups. Australians have had access to complementary medicines via multiple channels for many years with 52%⁵ reporting that pharmacy is their preferred place to buy them. This would indicate that consumers’ buying habits for purchasing complementary medicines in pharmacy is well established.

The supply of vitamins and mineral supplements as well as complementary medicines should be supported. The pharmacy environment provides the opportunity for consumers seek information and professional advice about the use of these products. Pharmacists are the medicines experts who could advise on

⁴ Macquarie University Consumer Factbook, March 2015  
⁵ Macquarie University Consumer Factbook, March 2015
possible interactions between various medicines. Should their chosen product be inappropriate then advice in community pharmacy is available to help with their selection.

**116. Should complementary products be available at a community pharmacy, or does this create a conflict of interest for pharmacists and undermine health care?**

ASMI considers that the availability of complementary medicine products in community pharmacy is appropriate – as discussed in question 115.

Complementary medicines should continue to be available in pharmacy given consumers’ desire to purchase them there (see question 115). Any product that is listed or registered on the ARTG can be legally sold in pharmacy and consumers would expect them to be available there. Like OTC and prescription products, consumers can benefit from the advice and knowledge that pharmacists can provide on various medicines. Pharmacy is an appropriate environment to sell all health related products because consumers will always have the opportunity of requesting advice for any product they wish to purchase, and the Pharmacist can redirect the consumer to a more appropriate option when needed.

ASMI does not believe that selling complementary medicines creates a conflict of interest for pharmacists. Pharmacists have a duty of care to consumers to provide advice and assistance when requested, and also to explain to consumers the evidence levels for the various products. Many complementary medicines have good evidence and Australia has a strong and effective regulatory environment in relation to these products. Most complementary medicines are listed on the ARTG, meaning that sponsors must comply with quality and manufacturing standards and hold evidence for efficacy. Some complementary medicines are registered, meaning that the TGA has assessed evidence for safety and efficacy. Many complementary medicines – both listed and registered – have strong evidence for their safety and efficacy and it is unhelpful to claim that it is a conflict of interest for pharmacists to supply these products. Pharmacists can be a good source of information to assist consumers in selecting appropriate options, if needed.

**Question 117. Do consumers appreciate the convenience of having the availability of vitamins and complementary medicines in one location? Do consumers benefit from the advice (if any) provided by pharmacists when selling complementary medicines?**

Pharmacists continue to be a trusted healthcare professional for consumers to turn to and are one of several sources of information that consumers use for complementary medicines. The network of community pharmacies provide consumers with an easily accessible health care professional who they can talk to regarding complementary medicines, as well as OTC and prescription medicines.

Consumers are in general very satisfied with the information and service provided by pharmacists and pharmacy staff, with the following notable findings:

- **73.5%** of consumers surveyed agreed with the statement “Pharmacist recommendations help me make the best choices”
- **72.8%** of consumers surveyed agreed with the statement “I usually follow the advice I’m given in the pharmacy”

Pharmacists and pharmacy assistants have access to education and information on complementary medicines and consumers benefit from the pharmacist being able to assist them with independent advice and recommendations on quality use of medicines, including complementary medicines.

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6 Macquarie University Consumer Factbook, March 2015
Question 118. Does the ‘retail environment’ within which community pharmacy operates detract from health care objectives?

The pharmacy retail environment needs to be conducive to enabling ‘health conversations’ with consumers. This includes having appropriate access to the pharmacist/pharmacy staff, being able to navigate the store, accessing appropriate health related products and being able to have discreet counselling conversations. The retail environment should provide the necessary layout, space and fittings to accommodate all of these needs. The products carried and ranged should also reflect this.