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20th July 2017

Pharmacy Review (MDP 900)
Department of Health
GPO Box 9848
Canberra ACT 2601

Dear Sir or Madam,

Re: ASMI Response to the Review of Pharmacy Remuneration and Regulation, Interim Report June 2017

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 non-prescription medicines

ASMI appreciates the opportunity to provide comment in relation to some of the options put forward in the Interim Report, and our comments are limited to areas where there is relevance to the non-prescription medicines industry and to consumers who use these products.

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,

[redacted]

Section 2.8 – Consumer Medicines Information (CMI)

OPTION 2-6: CONSUMER MEDICINES INFORMATION

A Consumer Medicines Information (CMI) leaflet should be offered and made available to consumers with all prescriptions dispensed in accordance with Pharmaceutical Society of Australia (PSA) guidelines. The PSA guidelines and the distribution of CMIs to consumers need to be audited and enforced to ensure compliance.

Pharmacists and the pharmacy industry should continue to work on the improvement of CMIs and the use of technology to make medicines information more available to consumers.

ASMI acknowledges that CMI provision plays an important role in providing information on medicines to consumers, and has been involved for many years in the development and implementation of CMI in the following ways:

- Development of Core CMI for non-prescription medicines
- Publication of Usability Guidelines and Core CMIs on ASMI website, as a service to industry
- Support and involvement in CMI research and quality assurance activities – including the Consumer Medicine Information Quality Assurance Reference Group (QARG) and the CMI Consistency Working Groups

ASMI supports Option 2-6, and acknowledges that while sponsors must make CMI available as part of their sponsor obligations [Therapeutic Goods Regulations (Cth) part 2, section 9(A)], pharmacists have legal and professional practice obligations for ensuring that consumers have sufficient information to enable them to use their medicines properly. This responsibility applies to both dispensed medicines as well as non-prescription medicines.

The PSA's Guideline, "Consumer Medicine Information and the Pharmacist[1]" clearly outlines the pharmacist's responsibilities and professional obligations. Although pharmacists are not legally required to supply a CMI leaflet to a consumer, pharmacists are encouraged to supply CMI and assist consumers to make informed decisions about their medicines. They can also supplement the CMI with other forms of medicine and health information (e.g. the Pharmacy Self Care Fact Cards) and assist consumers with highlighting relevant parts of the CMI.

Technology has allowed CMI to be made available for consumers though additional means, such as company websites, the TGA website, as well as other websites and Apps. ASMI believes that the CMI presentation requirements are rather prescriptive and can be repetitive, and more flexibility with CMI layout should be explored, so that CMI can be more easily optimized to suit mobile applications and new technologies, making it easier for consumers to access in different formats.

The TGA website CMI portal publishes CMI for prescription medicines, however it does not publish CMI for S3 medicines. ASMI supports the availability of CMI on the TGA website, and supports its expansion to include CMI for S3 medicines.

[1] Pharmaceutical Society of Australia. Consumer Medicine Information and the Pharmacist. January 2007. http://www.psa.org.au/wp-content/uploads/Guidelines-for-Pharmacists-Consumer-Medicines-and-the-Pharmacists-83kb3.pdf

In relation to the second part of Option 2-6, ASMI supports the recommendation that pharmacists and industry should continue to work together to improve CMIs as well as look at new technology to improve consumer access to information on medicines.

As an industry body that has made a significant contribution to the development and implementation of CMI materials, ASMI is continuing to be involved with the Electronic Distribution Working Group (EDWG) and Medicines Australia initiatives for continuing improvement of CMI and is keen to contribute to any further activities to enhance the quality and distribution of CMI.

Section 3.3 – Complementary medicines

OPTION 3-2: COMPLEMENTARY MEDICINES – SUPPLY FROM PHARMACIES

Community pharmacists are encouraged to:

a. display complementary medicines for sale in a separate area where customers can easily access a pharmacist for appropriate advice on their selection and use

b. provide appropriate information to consumers on the extent of, or limitations to, the Therapeutic Goods Administration (TGA) role in the approval of complementary medicines. This could be achieved through the provision of appropriate signage (in the area in which these products are sold) that clearly references any limitations on the medical efficacy of these products noted by the TGA.

Complementary Medicines (CMs) are an established part of the self-care environment. According to a 2015 study conducted by the Macquarie University Centre for the Health Economy[2], 70% of the adult population has used a vitamin, mineral or supplement (VMS) in the previous 12 months. ASMI also acknowledges that consumers place value on the pharmacist's advice, and that CMs are an integral part of the self-care environment.

ASMI does not support Option 3-2(a), which seeks to encourage pharmacists to display complementary medicines for sale in a "separate" area of the pharmacy. All listed and some registered CMs are exempt from scheduling (are "unscheduled" goods) and can legally be supplied in pharmacies as well as supermarkets, health food stores and online.

There should be no particular display or signage requirements imposed on pharmacy, given the multiple distribution and access channels available for these products. This would create inconsistent requirements across pharmacy and other distribution channels such as supermarkets and health food stores, where no such requirements would be applicable. Such inconsistencies can be confusing for consumers.

ASMI agrees that pharmacists are well qualified to provide advice on CMs and should be encouraged to communicate with consumers and provide advice on products as requested. One of the advantages of supply of these products through the pharmacy channel is that advice is readily available if required and the pharmacist can tailor their advice to the individual's health status, and consumers who would like access to advice will seek it out through the various information sources available to them, including their pharmacist. The advantage of the pharmacist is that they can personalise the advice to suit the consumer's individual health conditions or concerns.

[2] Macquarie University Centre for the Health Economy. Consumer Behaviour Factbook, March 2015

ASMI does not support Option 3-2 (b) and is concerned with the implication that CM products as a class have limited efficacy. Under Australian requirements, sponsors of listed complementary medicines must use only pre-approved, designated ingredients and are required to hold evidence to support the indications and claims for each product. Sponsors of registered CMs will have had full TGA evaluation of quality, safety and efficacy and the labels and indications for registered CMs are approved by the TGA

CMs are a diverse group of products – vitamins and minerals for supplementation – e.g. calcium, vitamin D, pregnancy and other multivitamins through to herbal medicines based on either scientific or traditional use. There are also some products that are in the food/medicine interface.

As a class, CMs are generally considered to be "low risk" medicines, suitable for use for supplementation or symptomatic relief of generally self-limiting conditions. Given the "low risk" nature of the products and their indications, the information required for safe use is on the product label. The TGA's legislative instrument, the *Permissible Ingredients List 2016*, (underpinned by s26BB of the Therapeutic Goods Act) provides detailed requirements on ingredients that can be used, the appropriate levels and any mandatory labelling requirements that relate to contraindications, warnings, precautions, dosage instructions.

Some CMs have also passed the TGA's post-marketing review process, and for these listed medicines the TGA has assessed and is satisfied with the quality of the evidence held by the sponsor. Other CMs are registered, meaning that the TGA has fully evaluated the quality, safety and efficacy of the medicine. The TGA website includes a list of registered CMs.

As briefly described above, the regulatory requirements underpinning CMs are complex. It is not only difficult, but also inaccurate to place signage in a pharmacy, that seeks to reference limitations on the efficacy of CM products as a class. The evidence varies from product to product, and for different treatment paradigms. Pharmacists should be sufficiently informed and prepared to provide individual health advice to consumers however a simple sign cannot convey the complexity of the regulatory framework and the evidence on any individual product.

The recent Review of Medicines and Medical Device Regulation ("the MMDR") also reviewed the TGA's legislative framework for all medicines, including CMs. Many recommendations on CMs were made, to which the Government has responded. Some regulatory reforms are currently being undertaken, including the creation of a Permitted Indications List and an additional "third" pathway for sponsors seeking TGA assessment of evidence for a new CM product.

Option 3-2 appears to be a simplistic response to some perceptions on the quality of evidence held by some sponsors. Some of these concerns were raised during the MMDR submission process. ASMI believes that it is the role of the regulator to address perceived gaps in the regulatory framework and that the TGA is working through the MMDR reform process, implementing changes to the regulatory framework to address some of these concerns.

The MMDR recommendations initially included the recommendation for "disclaimers" about efficacy claims to be required on labelling (see recommendation 44)[3]. The proposal in Option 3-2 (b) appears to reflect the same concept, i.e. examining ways of advising consumers that efficacy

[3] Expert Review of Medicines and Medical Devices Regulation. Stage 2, July 2015 http://www.health.gov.au/internet/main/publishing.nsf/content/8ADFA9CC3204463DCA257D74000EF5A0/$File/Review%20of%20Medicines%20and%20Medical%20Devices_Stage%20Two%20Report_Accessible.pdf

claims for CMs have not been evaluated by the TGA. It should be noted that this recommendation was rejected by the Government in its response to the review[4], and ASMI believes that the Review into Pharmacy Regulation and Remuneration should align with the government's already stated views on this matter.

ASMI supports education and improved health literacy of consumers, however pharmacy layout and simplistic, potentially misleading signage are not appropriate means of achieving improved quality use of CMs and improving consumer knowledge.

3.4 Pharmacy Only (S2) and Pharmacist Only Medicines (S3)

OPTION 3-3: PLACEMENT OF PHARMACY ONLY AND PHARMACIST ONLY (SCHEDULE 2 AND SCHEDULE 3) MEDICINES WITHIN A PHARMACY

Access to Pharmacy Only (Schedule 2) and Pharmacist Only (Schedule 3) medicines should be clearly separated from complementary medicines within a pharmacy. Options to achieve this might include:

a. ensuring that all Pharmacy Only (Schedule 2) and Pharmacist Only (Schedule 3) medicines only be accessible from 'behind the counter' in a community pharmacy so that a consumer must always seek assistance or advice in obtaining these medicines

b. requiring that complementary medicines are not displayed 'behind the counter' in a community pharmacy.

ASMI has concerns with the opening statement of the discussion relating to this section, that "Complementary medicines pose a risk to consumers when they are not clearly separated from Pharmacy Only and Pharmacist Only medicines". We believe that the statement does not articulate what the perceived risk is; it is also inaccurate, since CMs are classed by the TGA as "low risk medicines" that must use designated, pre-approved ingredients. Considering that the majority of CMs are unscheduled medicines, they are also considered to be suitable for consumers to self-select using labelling information. CMs are also available through a variety of distribution channels, which does not apply to S2 and S3 medicines.

The Review does not differentiate between CMs. Many of the comments and options in the paper conflate all CMs – vitamins, minerals, herbal medicines as well as registered and listed CMs. ASMI believes that a more nuanced and evidence based approach would have been more appropriate.

The scheduling framework clearly sets out the level of access for medicines, and any recommendations for product location within pharmacy should be consistent with the scheduling framework and the various State and Territory legislative requirements. Most pharmacies separate CMs from other medicines that are stored either behind the counter or in the pharmacist advice section; however, this is not and should not be a legislative requirement.

ASMI does not support Option 3-3 (a), that states that all S2 and S3 medicines should only be accessible from "behind the counter". This position is inconsistent with the Scheduling Factors for Schedule 2 medicines described in the Scheduling Policy Framework[5], which state that S2 medicines are used for conditions that can be managed by the consumer without the need for medical intervention, and that the availability of a pharmacist at the point of sale supports the

[4] Australian Government Response to the Review of Medicines and Medical Devices Regulation. https://www.tga.gov.au/sites/default/files/australian-government-response-mmdr-2016.pdf
[5] AHMAC Scheduling Policy Framework. Feb 2015. https://www.tga.gov.au/book/chapter-3-classification-medicines-and-chemicals-schedules

consumer in selecting and using the appropriate medicine. These medicines are suitable for self-selection, with support from the pharmacist if required. S2 medicines are not the same as S3 medicines, which require the pharmacist to be involved with supply.

ASMI does not agree that the same storage and accessibility requirements should apply to S2 and S3 medicines. This is inconsistent with the different risk profile and scheduling factors for each of these different schedules, and it is inconsistent with the way that pharmacists and pharmacy staff handle the requests for these products. Consumers do not require pharmacist counselling and verification of the condition with every request for a S2 medicine.

The majority of State and Territory Poisons Regulations (NSW, Victoria, SA, Tasmania, NT and ACT) allow S2 medicines to be stored close to or next to the dispensary, or on a wall behind the front counter in front of the dispensary. Storage in this manner enables the pharmacist and pharmacy assistant to appropriately monitor the use of these medicines and to offer advice when needed.

Ideally, storage requirements that reflect the different ways S2 and S3 medicines are supplied should be aligned across all jurisdictions to enable uniformity across pharmacies. ASMI supports alignment of WA and Queensland with the other States and Territories, which more appropriately reflect these differences.

5.10 – Variations among State and Territory arrangements relating to community pharmacy

OPTION 5-9: HARMONISING PHARMACY LEGISLATION

As early as practicable, the Australian Government, through the Australian Health Minister's Advisory Council, should seek to harmonise all state, territory and federal pharmacy regulations to simplify the monitoring of pharmacy regulation in Australia for the safety of the public.

In the long term, a single pharmacy regulator could be considered.

As an interim measure, state and territory registering bodies need to coordinate with the Australian Health Practitioner Regulation Agency to ensure that pharmacy regulations are being adequately monitored for best practice of pharmacy and the safety of the public.

ASMI supports harmonisation of State and Territory legislation especially in relation to distribution and storage of medicines, and to the jurisdictional requirements for storage of S2 medicines. As stated above, ASMI supports alignment of WA and Queensland requirements with those of most States and Territories, which allow S2 medicines to be stored close to or next to the dispensary. This approach clearly reflects the differences between S2 and S3 medicines and the way these are supplied to the consumer.

Harmonisation of requirements for distribution, storage and dispensing of medicines will have benefits for consumers, who would expect that access and availability of medicines is uniform across States and Territories, but also for locum pharmacists and doctors who work across the different jurisdictions. Harmonisation of requirements is also beneficial for industry, as it allows displays and planograms to be uniform across all States and Territories. It would also eliminate the need for companies to develop specific point-of-sale display materials for those states where S2 medicines are stored behind the counter, and are therefore not available for consumers to self-select medicines or read the labels of S2 medicines by themselves.

ASMI has no specific comments regarding other parts of the State and Territory regulation such as regulation of pharmacy premises, dispensing of S4s and S8s, but notes that jurisdictional

differences create complexity for businesses as well as pharmacists and doctors who may wish to conduct business or work across different States and Territories.

Section 10-5 – Tightening the listing of generic medicine

OPTION 10-5: GENERAL MEDICINE – LISTING ARRANGEMENTS
When an 'original' (or 'branded') medicine comes off patent then the government should hold a tender for the listing of generic versions of the medicine. The government should limit the number of generic versions of a particular medicine to be listed to a relatively small number that is still sufficient to allow for patient choice (e.g. four generics and the original brand of the medicine). The chosen generics should be those best able to meet the distribution and other conditions required by the government at the least cost to the PBS.

ASMI has no specific comments in relation to PBS listing of generics, however we would like to make some general observations in relation to Option 10-5.

Although the proposed listing arrangements in Option 10-5 are made in the context of PBS listing, it should also be noted that there are many generics of OTC medicines, for example different pharmacy brands/banner group brands of various commonly used pain relievers, anti-allergy medicines, antifungal products. ASMI opposes restrictions being placed on the number of brands or generic products for non-prescription medicines; this would place undesirable restriction on competition and result in less choice for consumers.

We also question whether any restrictions or limits on registration or PBS listing of generics represents imposition of unfair limits on competition. Any potential anti-competitive elements of Option 10-5 should be further explored, as it contrasts with the ACCC's public position on competition[6] which states that any business practices that limit or prevent competition are illegal.

Section 10-6 – Machine dispensing

OPTION 10-6: MACHINE DISPENSING
The government should trial the use of machine dispensing in a small number of relevant secure locations in communities that are not currently adequately served by community pharmacy. Such machine dispensing should be appropriately supervised and allow real-time interaction with a remote pharmacist. The range of PBS medicines available through machine dispensing also needs to be limited and should be based on an assessment of risk.

ASMI notes with interest the commentary on machine dispensing.

While we have no specific comment in relation to machine dispensing, we note that State and Territory legislation currently precludes access to S2 or S3 medicines through machines.

Any further discussion of remote or machine access to medicines should involve a detailed analysis of risk and benefit and should also include non-prescription medicines. There should also be transparent consultation on any update to the legislative framework that may enable remote access.

[6] Australian Competition and Consumer Commission. https://www.accc.gov.au/business/anti-competitive-behaviour