Attachment 2

ASMI proposal to introduce

an alternative regulatory model for the advertising of Pharmacist Only Medicines

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

A proposal to introduce an alternative regulatory model for the advertising of Pharmacist Only Medicines

Introduction

The ageing population and increasing burden of disease pose enormous challenges for continuing to provide health services at sustainable levels. Empowering consumers to take more responsibility for their health and measures to make better use of scarce healthcare resources are some of the policy responses to these challenges.

It is recognised that community pharmacists are a vastly under-utilised resource and by expanding their professional role they are well-placed to play a greater part in the delivery of primary healthcare. This will have the added benefit of reducing the burden on GPs, freeing up their time to manage more serious conditions.

The wider availability of efficacious 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.

Current arrangements

Under the Therapeutic Goods Legislation a Pharmacist Only (Schedule 3) Medicine is not permitted to be advertised directly to consumers, unless an exemption has been granted. Appendix H of the SUSMP lists the Schedule 3 medicines for which exemptions have been granted. No other Schedule 3 medicines may be advertised to consumers, despite being available without a prescription.

The inability of sponsors to create consumer awareness of Schedule 3 medicines is the main reason why in Australia the full potential of Schedule 3 medicines as legitimate treatment option has not been realised.

Impact of current arrangements

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, based on the classification criteria established under the medicines scheduling framework and the mandatory involvement of a pharmacist in the supply of these products.

The restrictions have a negative impact. They constrain the ability to make consumers aware of medicines which are available without a prescription. Consequently, consumers continue to consult GPs for conditions which could be safely managed by pharmacists.

An alternative regulatory model

The proposed model is based on a framework that provides for information to be provided in a structured and balanced way. The primary aim is to create consumer awareness of therapeutic options in Schedule 3 and to encourage consumers to seek counselling by a pharmacist. The desired outcome is better informed consumers.

Key aspects of the proposed model:

1. The **default** regulatory position is that all Schedule 3 should be permitted to be advertised. This will permit the advertising of Proton Pump Inhibitors (PPIs) for gastro-oesophageal reflux disease (GORD), combination ibuprofen plus paracetamol, and higher strength non-steroidal anti-inflammatory medicines.
2. Provision for **exceptions**, on a case-by-case basis, where it can be demonstrated that direct-to-consumer advertising would not be in the public interest, e.g. products containing pseudoephedrine and codeine containing analgesics.
3. A structured communication format containing the following 3 components:
   - **Information about the condition:** this aims to inform consumers about the symptoms and/or condition for which the product is indicated.
   - **Mandatory intervention by a pharmacist:** this component of the communication strategy/process aims to promote and reinforce the professional role of the pharmacist. It will emphasise the need for counselling to determine whether the product is appropriate for a particular condition and/or consumer and aims to clarify that a product request does not automatically result in the supply of that product.
   - **Branded product information:** the brand awareness component is a critical element to make the model viable, but it takes a secondary role to the more important educational aspects of the communication.
4. Regulatory controls: The definition of an advertisement in the Therapeutic Goods Legislation is very broad and will automatically capture all communications directed to consumers under the proposed model. Consequently, all existing regulatory controls will provide the necessary checks and balances to ensure compliance. The following controls are already in place:
   - The Therapeutic Goods Advertising Code (TGAC). It is envisaged that a specific section on advertising of Pharmacist Only Medicines will be incorporated into the TGAC to ensure universal application;
   - Current mandatory pre-approval of advertisements in specified media;
   - Existing co-regulatory complaints handling by the Complaints Resolution Panel (CRP); and
   - Existing self-regulatory mechanisms in industry codes of practice.

Summary

Preventing consumer awareness of safe and efficacious medicines, which are available without a prescription and for which pharmacists are the gatekeepers, does not support desirable health outcomes.

The proposed regulatory model provides 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.