



7 November 2012

Comments by the Pharmacy Guild of Australia on Over-the-Counter (OTC) Medicines Business Process Reform

Background

The Pharmacy Guild of Australia (Guild) welcomes the opportunity to comment on the Over-the-Counter (OTC) Business process Reform Consultation Paper (version 1.0 September 2012) (Consultation Paper) prepared by the Therapeutic Goods Administration (TGA).

The Guild is an employer organisation servicing the needs of independent community pharmacies. It strives to promote, maintain and support community pharmacies as the most appropriate primary providers of health care to the community through optimum therapeutic use of medicines, medicines management and related services.

Quality Use of Medicines

Quality Use of Medicines (QUM) is one of the central objectives of Australia's National Medicines Policy¹. The Guild believes that QUM is best supported by the supply of medicines through a pharmacy where there is access to professional support and advice from a pharmacist, with assistance provided from trained pharmacy assistants.

It should be noted that community pharmacy maintains a high standard of patient care with the Quality Care Pharmacy Program (QCPP) which is recognised as the Australian Standard² for service provision within the community pharmacy sector. By contrast, there are no controls or quality assurance processes in place for the supply of medicines outside of the pharmacy sector.

Medicines Access Overview

Medicines are not normal products of commerce, having the potential to do significant harm if used incorrectly or inappropriately. Consumers need and want advice on the correct and proper use of medicines and this is best achieved with supply through the pharmacy sector.

The use of and access to medicines in Australia is changing, with the population ageing and consumers contributing more and more to the cost of medicines.³ It is essential to protect the most vulnerable consumer groups, particularly children, the elderly, those from poorer socio-economic backgrounds or those who do not speak or understand English well. Providing consumer access to information via hand-outs or labelling is not enough. Facilitating access to professional advice for the prescribing and supply of

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medicines is the best way to maintain safe and cost-effective access to medicines for optimal health outcomes.

The high incidence of polypharmacy warrants health professional advice on the use of OTC medicines as well as prescription medicines. Research conducted by the NPS in 2011 reported that 60% of the 1500 consumers surveyed had used an OTC medicine in the last 3 months.⁴ A recent random cross-sectional survey⁵ of Australians aged 50 years and over reports that nearly 85% of medicines used were purchased from a pharmacy. The remainder were purchased from supermarkets (7%), health food stores (5.4%) and the internet (0.7%).

Comments

Noting that the Business Process Reform has application primarily to industry in registering OTC medicines for sale in Australia and New Zealand, there is some impact on how these medicines are marketed at the consumer level for which the Guild has provided comment. Community pharmacy is the primary supplier of OTC medicines to consumers, and the Guild wants to ensure that the framework supporting how OTC medicines are developed, registered and marketed is consistent with QUM principles so that community pharmacists can meet their professional obligations when supplying OTC medicines.

1. Objectives of the new Business Process Reform

The Guild supports business process reforms that improve the efficiency and cost-effectiveness of developing, registering and marketing OTC medicines. Maintaining an effective and viable OTC medicine category supported by a professional and well-trained community pharmacy workforce is cost-effective for public health expenditure.

2. Proposed Risk Categorisation Framework

The Guild agrees in-principle with the concept of risk-based categories for OTC medicines and the proposed risk categories for new and changed medicines. We are interested though on what population group the risk is based on. The level of risk varies according to the population group considered.

Given Australia's ageing population, the greater incidence of chronic illness and poor health-literacy levels, we believe that groups such as the elderly and CALD are higher risk categories. Similarly children and people using multiple medicines are higher risk categories.

While the 'Likelihood : Consequence' risk matrix seems sensible, we note in the 'Introduction and overview' of the Consultation Paper that 'the objective of the medicines legislation in both countries is to protect public health by managing the risk of avoidable harm associated with the use of medicines'. As such, we believe risk should be considered with respect of the most vulnerable population groups for which the product is likely to be used. This means for example, with a new OTC application for an analgesic for arthritic pain, the risk category should be considered with regards to likelihood and consequence of adverse health outcomes for an elderly person taking chronic medicines rather than a healthy young adult.

We are also interested in how the Risk Categorisation Framework may integrate with the Scheduling Framework⁶ and the use of the OTC scheduling system as a risk management approach for access to medicines and professional support.

3. OTC Medicine Monographs

The Guild supports the development of monographs for OTC medicines and we note that the current proposed selection are among the most commonly available products which, with the exception of paracetamol and codeine, are available from the grocery sector.

We suggest that as a priority, medicines that are exempt from scheduling should have a monograph, including nicotine, phenylephrine and guaiphenesin as well as recently exempted medicines such as fexofenadine, cetirizine, loratadine and loperamide.

4. Umbrella Branding

Umbrella branding is a form of brand extension referring to the use of a successful brand name to market a new or modified product. Umbrella branding is becoming more common within the competitive market place and the Guild is concerned that there are many OTC medicines coming onto the market under ‘Umbrella Branding’ that poses a public health risk.

We agree with the distinction between ‘House Brand’ and ‘Umbrella Brand’; however, we also believe that it is essential to clearly define what sort of Umbrella Branding is permitted. The Guild acknowledges and supports the use of Umbrella Branding in the following circumstances:

- For products containing the same active ingredient and marketed for the same indications but with different excipients (e.g. different flavoured products, such as Strepsils[®], or products with different colouring agents or sugar content, such as Panadol[®] elixir).
- For products containing the same base ingredient as well as additional ingredients to extend the indicated use of the product (e.g. paracetamol + codeine for moderate pain relief or ibuprofen + phenylephrine for cold and flu symptoms).

However, we do not support Umbrella Branding for products containing the same active ingredient (or salt of) that is labelled and marketed for different indications (e.g. products containing ibuprofen salts marketed as distinct products specifically for pain and inflammation, migraine, backache, period pain). Consumers may not realise the same medicine is included in each of these products and take the same drug for different indications, increasing the risks of adverse effects and overdose. The people particularly at risk of adverse effects are also the most vulnerable population groups who usually have the poorest health literacy. In addition, many of these umbrella branded products are exempt from scheduling, meaning they are available from retail outlets where there is no access to professional advice and information.

Reference Sources:

- ¹ <http://www.health.gov.au/internet/main/publishing.nsf/Content/National+Medicines+Policy-1>
- ² Australian Standard® AS 85000-2011 Quality care Pharmacy Standard – quality management system for pharmacies in Australia
- ³ Australians paying for medicines – new research; AHHA 13/09/2011; <http://ahha.asn.au/news/australians-paying-more-medicines-new-research>
- ⁴ NPS Media Release – New survey shows Australians are not medicinewise; 30 Jan 2011;
- ⁵ TK Morgan, M Williamson, M Pirotta; A national census of medicines use: a 24-hour snapshot of Australians aged 50 years and older; MJA 2012; 196(1):50-53
- ⁶ <http://www.tga.gov.au/industry/scheduling-spf.htm>