



The Pharmacy  
Guild of Australia

**Pharmacy Guild submission in response to**

**The Productivity Commission- Issues Paper:  
The Economic Structure and Performance of the  
Australian Retail Industry**

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**National Secretariat**

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## Introduction

### The Pharmacy Guild of Australia

The Pharmacy Guild of Australia (the Guild) is the national peak pharmacy organisation representing community pharmacy. It strives to promote, maintain and support community pharmacies as the most accessible primary providers of health care to the community, through optimum therapeutic use of medicines, medicines management and related health care services.

### Background

The Guild welcomes the opportunity to provide input into the Productivity Commission's investigation into the economic structure and performance of the Australian retail industry. We note the terms of reference, as set for the Productivity Commission, are to examine:

1. The current structure, performance and efficiency of the retail sector and impediments to its contribution to the Australian economy
2. The drivers of structural change in the retail industry, including globalisation, increasing household and business access to the digital economy, cost structures of the domestic retail industry, employment structure, the exchange rate and structural change driven by the resources boom
3. The broader issues which are contributing to an increase in online purchasing by Australian consumers and the role of online purchasing in providing consumers with greater choice, access and convenience
4. The sustainability and appropriateness of the current indirect tax arrangements in this environment, including the impact on Commonwealth and State and Territory budgets, and the extent to which technology could reduce the administrative costs of collecting indirect taxes and duty on imported goods
5. Any other regulatory or policy issues which impact on structural change in the sector.

The Guild also notes the following excerpt, from page 5 of the accompanying issues paper:

“... the Commission does not intend to examine broader policy issues associated with pharmaceutical retailing. Pharmacies are specialist outlets with complex connection to broader public health policies such as the pharmaceutical benefits arrangements. However, pharmaceutical retailing is an area where competition from discount pharmacies and legitimate internet suppliers of prescription and non-prescription medicines is growing. This inquiry may address these and other aspects of the sector.”

### Scope of this Comment

As described in the excerpt above, there is continuing growth in the area of online supply of medicines. It is this area the Guild provides comment on in this paper and, more broadly, issues relating to point 3 in the above terms of reference, concerning the role of online purchasing as it relates to medicines. Amongst the concerns detailed below under “Comments”, the Guild also addresses the following questions, from page 19 of the accompanying issues paper:

***Are there adequate protections for Australian consumers purchasing goods from overseas websites online? If not, what can be done to improve consumer protection for online purchases from overseas websites or to better educate consumers to help them avoid detriment?***

***Are there any significant examples of problems with regard to the safety, quality or performance of goods purchased by Australians from overseas online traders?***

## Comments

### General

The Guild's comments concerning the online supply of medicines are underpinned by our commitment to Quality Use of Medicines principles and support of the legislative framework governing the supply of therapeutic goods in Australia.

### Quality use of Medicines

Quality Use of Medicines (QUM) is one of the central objectives of the Australian Government's National Medicines Policy<sup>1</sup>. It concerns:

- selecting patient management options wisely (management may or may not require medicines);
- choosing suitable medicines (if medicines are considered necessary); and
- using medicines safely and effectively to get the best possible results, by monitoring outcomes and minimising over-use, under-use and misuse

Thus, QUM principles dictate that health professionals, including community pharmacists, supply patients/consumers with the appropriate medicines, in the appropriate circumstances, with variables such as the individual's circumstances, clinical condition and all risks and benefits taken into account. Therefore, whilst for the purposes of this consultation, medicines can be considered a 'retail good', QUM principles mean they are very much distinct from other retail goods, which lack such controls and professional intervention.

### *Guild concerns relating to online medicine sales and QUM*

The Guild remains strongly committed to the application of QUM principles in all areas relating to medicines supply, and it is this commitment that underpins our concerns surrounding the online supply of medicines.

Globalisation and associated e-commerce has facilitated the sale of goods and services across international borders, and medicines are no exception. Thus, the internet has allowed consumers direct access to medicines, often from overseas sources, without (in many cases) consultation with a health professional and the provision of the QUM principles previously detailed. This type of access might confer greater convenience in the minds of consumers, but people run the risk of being supplied with medicines that are not suitable for their condition, have inappropriate adverse effects or interact with other medicines they are taking. There are many instances where, because of a pharmacist's intimate knowledge of a consumer's medicine regimen and personal medical history, potentially serious complications have been avoided. This personal contact is not maintained through internet pharmacy.

The Guild maintains that the ideal way to supply and receive medicines is through face-to-face contact. The opportunity to receive supplementary advice and/or counselling from a pharmacist or trained pharmacy staff member can provide significant benefits for consumers, per QUM principles. This is consistent with the Pharmacy Board of Australia's 'Guidelines for Dispensing of Medicines' which describes online sales of medicines as 'less than the optimal way of delivering a pharmacy service, because communication may be compromised'.<sup>2</sup> The Guild also remains

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<sup>1</sup> National Medicines Policy- Quality Use of Medicines

[www.health.gov.au/internet/main/publishing.nsf/Content/national-medicines-policydoc~national-medicines-policy-5](http://www.health.gov.au/internet/main/publishing.nsf/Content/national-medicines-policydoc~national-medicines-policy-5)

<sup>2</sup> Page 2 of Guidelines for Dispensing of Medicines- accessible at <http://www.pharmacyboard.gov.au/Codes-and-Guidelines.aspx>

concerned at the possibility that online supply of medicines may contribute to QUM principles being undermined in terms of the number of packs of a medicine that may be supplied, both in the case of over-the-counter (OTC) and prescription medicines. Anecdotal reports suggest some online pharmacies actively promote the dispensing of multiple repeats as a means of cost-saving or convenience to the patient- these are not acceptable reasons for such supply and increase the risk of medicine misuse.

We note that there are circumstances (such as in the case of patients in rural/remote areas) where online access might be necessary and appropriate. In cases of medicine supply from an Australian online or mail order source, the pharmacist must "comply with all relevant State/ Territory/ Commonwealth legislation, Pharmacy Board Guidelines for Dispensing of Medicines, and established practice and quality assurance standards".<sup>3</sup> For example, the Pharmacy Guild's 'Quality Care Pharmacy Program' is accredited as the Australian Standard for community pharmacy practice; one of the mandatory actions for pharmacies to achieve accreditation is "Maintain and follow a system for distance supply, including internet pharmacy" which incorporates a distance supply checklist.

### Supply of Therapeutic Goods in Australia

The supply of therapeutic goods in Australia is regulated under the *Therapeutic Goods Act 1989*, (the Act) which is administered by the Therapeutic Goods Administration (TGA). Under the Act, prescription and OTC medicines, medical devices and complementary/alternative medicines (CAM) must be included on the Australian Register of Therapeutic Goods (ARTG) before being made available within, or exported from, Australia.

Australia has a two-tiered system for the regulation of these medicines, as follows:

- Higher risk medicines must be 'registered' on the ARTG, which involves the TGA individually evaluating the quality, safety and effectiveness of the product
- Lower risk medicines (eg most CAMs) containing pre-approved, low-risk ingredients and that make limited claims can be 'listed' on the ARTG.<sup>4</sup>

Medicines are also classified into schedules according to the level of regulatory control over the availability of the medicine, required to protect public health and safety. This ranges from schedule 2 (pharmacy only medicine), schedule 3 (pharmacist only medicine), schedule 4 (prescription only) and schedule 8 (controlled drug). Medicines that are exempt from scheduling are deemed substantially safe to also allow supply through non-pharmacy outlets such as the grocery sector or health food stores.

In regards to the manufacturing of medicines, the Act requires, with certain exceptions, that manufacturers of therapeutic goods hold a licence. To obtain a licence to manufacture therapeutic goods, a manufacturer must demonstrate, during a factory audit, compliance with manufacturing principles which includes relevant Codes of Good Manufacturing Practice (GMP) and Quality Systems. Overseas manufacturers of therapeutic goods supplied to Australia are also required to meet an acceptable standard of GMP comparable to that required by Australian manufacturers. Sponsors of overseas manufacturers must provide evidence acceptable to the TGA that the goods are manufactured to a standard of GMP equivalent to that expected of Australian manufacturers of the same goods. If acceptable documentary GMP evidence cannot be provided, the TGA will undertake on-site audits in the same manner as that conducted for the Australian manufacturers.<sup>5</sup>

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<sup>3</sup> Ibid.

<sup>4</sup> TGA- 'Regulation Basics'- [www.tga.gov.au/industry/basics.htm](http://www.tga.gov.au/industry/basics.htm)

<sup>5</sup> TGA- Good Manufacturing Practice for therapeutic goods- [www.tga.gov.au/industry/manuf-gmp-tg.htm#aust](http://www.tga.gov.au/industry/manuf-gmp-tg.htm#aust)

### ***Guild concerns relating to online medicine sales in the context of supply of therapeutic goods in Australia***

The above regulatory framework is designed to ensure the quality, safety and (in the case of registered medicines) efficacy of medicines for Australian patients/consumers. If a product is a therapeutic good and not included in the ARTG, as is the case with medicines imported from overseas via the internet, it is, by default, unapproved and unevaluated and, as such, may pose a public health risk. Sourcing medicines in this way undermines the entire purpose of the regulatory framework and the protection of public health it entails.

The TGA warns consumers of the dangers of purchasing medicines over the internet. They point out that products purchased in this way may contain unauthorised and potentially harmful ingredients. Recent examples through December 2010 to April 2011 include alternative medicines claiming to be 'natural' or 'herbal' which were found, upon TGA analysis, to contain prescription only agents used in medicines marketed for weight loss and erectile dysfunction.<sup>6</sup> Indeed, the prescription-only agent sibutramine, discovered in a purported 'herbal' weight loss product called 'Slimming Factor' in December 2010, had previously been withdrawn from the Australian market due to safety concerns. The other active ingredients in 'Slimming Factor', fenfluramine and phenolphthalein, had also previously been withdrawn from US and Australian markets due to safety concerns.<sup>7</sup>

### **Counterfeit Medicines**

Consistent with the Guild's concerns surrounding QUM and the supply of therapeutic goods previously outlined, consumers who purchase medicines from unknown/unverified sources, such as many overseas-based websites, also run the risk of receiving counterfeit medicines. This could result in products being at best ineffective, and, at worst, highly dangerous. The Guild notes the seriousness of the problem of counterfeit medicines around the world. The World Health Organisation (WHO) estimates that up to 1% of medicines available in the developed world, and 10% globally, are likely to be counterfeit<sup>8</sup>, whilst the US Centre for Medicine in the Public Interest estimated the global sale in counterfeit drugs was worth US\$75 billion in 2010<sup>9</sup>. The International Pharmaceutical Federation points out that medicines purchased over the Internet from sites that conceal their actual physical address are counterfeit in over 50% of cases.<sup>10</sup>

According to the TGA, counterfeit products detected in Australia are generally 'lifestyle' medicines, such as those for weight loss, hair loss and erectile dysfunction, however, we are concerned to note an increase of counterfeit medicines in the United Kingdom for products supplied in Australia on the Pharmaceutical Benefits Scheme, such as Lipitor®, Zyprexa®, Plavix® and Serotide®<sup>11</sup>.

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<sup>6</sup> See TGA Current Year Alerts and all alerts - [www.tga.gov.au/safety/alerts-current.htm](http://www.tga.gov.au/safety/alerts-current.htm) and [www.tga.gov.au/safety/alerts-all-date.htm](http://www.tga.gov.au/safety/alerts-all-date.htm)

<sup>7</sup> 'Slimming Factor TGA' safety advisory December 2010- [www.tga.gov.au/safety/alerts-medicine-slimming-factor-101223.htm](http://www.tga.gov.au/safety/alerts-medicine-slimming-factor-101223.htm)

<sup>8</sup> Counterfeit medicinal products – TGA news; Issue 58 April 2009 [www.tga.gov.au/newsroom/tga-news-2009-58.htm](http://www.tga.gov.au/newsroom/tga-news-2009-58.htm)

<sup>9</sup> Fake medicines: illegal, immoral and liable to increase drug resistance; April 2010; [www.cmpi.org](http://www.cmpi.org)

<sup>10</sup> International Pharmacy Federation: [www.fip.org/menu\\_counterfeitmedicines\\_policy](http://www.fip.org/menu_counterfeitmedicines_policy)

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<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/Counterfeitmedicinesanddevices/index.htm>

Currently, most of the counterfeit products that enter Australia are imported mistakenly in small quantities for personal use by individuals making a purchase via the internet, or by travellers who made the purchase while travelling overseas.<sup>12</sup>

## Regarding Questions

*Are there any significant examples of problems with regard to the safety, quality or performance of goods purchased by Australians from overseas online traders?*

As outlined, there are clear safety issues with regards to the purchase of medicines by Australians from overseas online traders. Purchasing medicines in this way:

- removes or reduces health professional involvement and associated QUM
- circumvents the Australian regulatory framework governing the supply of medicines, which is designed to maximise safety for consumers
- can lead to receipt of counterfeit medicines which can lead to ineffective or dangerous outcomes

The TGA continues to identify specific safety and quality issues with medicines bought in this way.<sup>13</sup>

*Are there adequate protections for Australian consumers purchasing goods from overseas websites online? If not, what can be done to improve consumer protection for online purchases from overseas websites or to better educate consumers to help them avoid detriment?*

The Guild believes that more can be done to protect Australian consumers, and in so doing, assist stakeholders, industry and regulators/government alike. These measures are outlined below.

## Suggested Measures re online selling of medicines (some may only be applicable to sites based in Australia)

- Stakeholders and regulators need to cooperate to move towards consistent, verifiable accreditation standards for all pharmacies selling medicines online
- Increased public awareness must be achieved via education programs, to warn consumers about the potential dangers of purchasing medicines over the internet.
- A comprehensive medicines anti-counterfeiting strategy should be developed by the regulatory body, in consultation with stakeholders- the United Kingdom's medicines regulator's strategy provides a good reference point<sup>14</sup>
- There should be regular checks and monitoring of internet sites selling medicines (this would become more effective under a national sale of medicines online accreditation standard)
- Measures requiring e-pharmacies to have processes for consumers to have a meaningful consultation with a pharmacist should be put in place
- Regulations that promote face-to-face interaction between a health professional and consumer wherever possible should be put in place- for example, all internet or mail-orders for medicines that have the potential for abuse/misuse to be accompanied by a prescription.
- Prescribers should be informed of relevant regulations in relation to online purchasing of medicines, to facilitate QUM.

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<sup>12</sup> TGA- Counterfeit medicines and devices- [www.tga.gov.au/consumers/information-counterfeit.htm](http://www.tga.gov.au/consumers/information-counterfeit.htm)

<sup>13</sup> Op. cit.- TGA Current Year Alerts.

<sup>14</sup> MHRA Anti-counterfeiting strategy accessible at [www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/Counterfeitmedicinesanddevices/index.htm](http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/Counterfeitmedicinesanddevices/index.htm)

- Action should be taken to ensure online pharmacies and internet sites are complying with the requirements relating to the supply of medicines, according to their schedule in the Schedule for the Uniform Scheduling of Medicines and Poisons (SUSMP)

## **Conclusion**

The Guild is concerned that the growing trend of the sale and purchase of medicines over the internet, within Australia and particularly internationally, creates an environment conducive to the uncontrolled and unregulated supply of medicines, as well as the potential for the supply of substandard and/or counterfeit medicines. With this in mind, we include the suggestions above and urge regulatory bodies to continue to take steps, with the cooperation of stakeholders, to monitor and regulate the online purchasing of medicines, and educate consumers on its inherent dangers. Importantly, whilst medicines can be loosely categorised as a retail good, the fundamental danger their unregulated supply represents means action in this area is more important than for other retail goods.