Letter

TGA Reform and Why You Should Care About It.

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Summary: the bill to amend the Therapeutic Goods Act was referred to the Senate for enquiry in late 2017, and since has been passed with further amendments. The bill triggered outcry by stakeholders who voiced concern that some of the proposed amendments may make the already widely criticised system, even worse.

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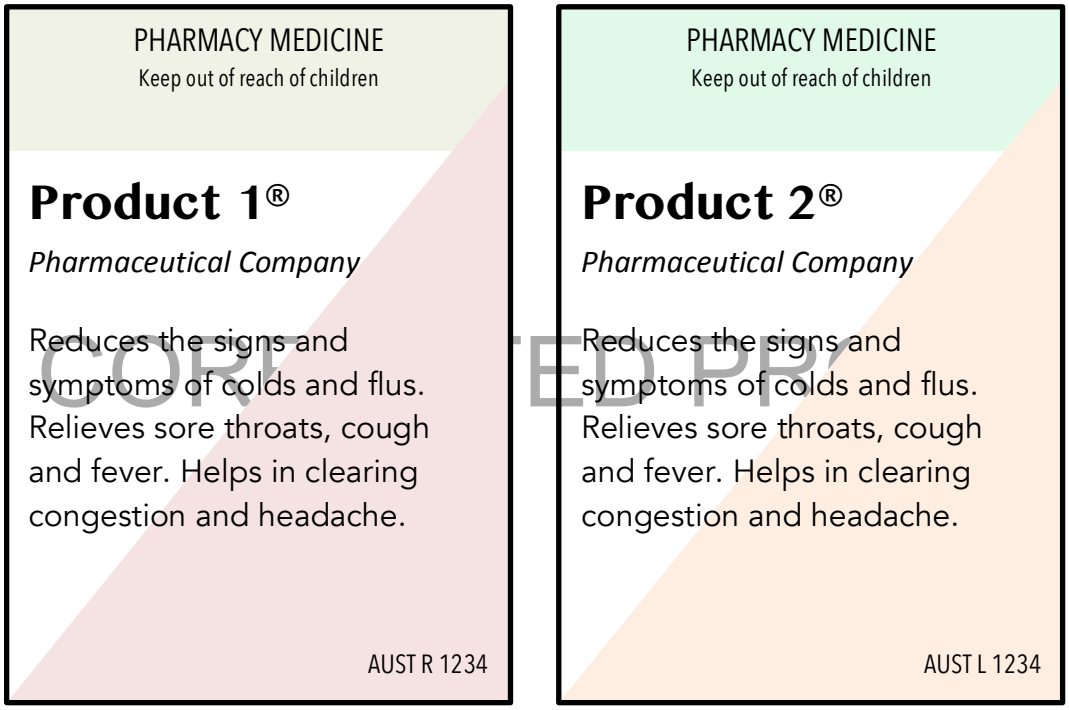
TGA reform and why you should care about it

How potentially dodgy products end up on your pharmacy shelf and how to tell which ones to trust.

Whilst consumer law hardly seems like a topic to engage doctors and medical students, the changes to the Therapeutic Goods Act have great significance for all healthcare professionals.

The Therapeutic Goods Act contains the rules and regulations that determine, which pharmaceutical products are sold in Australia, and what health claims they can make. When shopping in a pharmacy, most consumers and patients assume that the products available to them have been assessed for their safety and efficacy, which is not always the case [1,2].



Compare the 2 products above: Same store, same price, same therapeutic claims.

Yet only one product has ever had to demonstrate any evidence that it works to end up on your pharmacy shelf with the letter ”R”, the other end up with a letter “L”. One little letter, a lifetime of difference.

When a product is *registered* with the Therapeutic Goods Administration (TGA), the sponsor must provide high quality evidence to support any claims it makes; however, when a product is *listed* with the TGA, sponsors are only required to *say* that they do hold evidence to support their claims. At no point are they required to produce this evidence; and no part of the process checks that this evidence actually exists [2].

How do consumers tell the difference between registered and listed products? A tiny “AUST **R”** label for *registered products* and an “AUST **L”** for *listed products* is the

only indicator on the packet. A survey conducted by CHOICE in 2016 found that 80% of consumers were unaware that products had these codes on the label [4]. Even when the labels were pointed out to consumers, most were unsure of what "AUST R" and "AUST L" meant [4].

Both registered and listed products represent a substantial component of Australian patients' healthcare. Consumers spent roughly $10.8 billion on vitamins, supplements and over-the-counter medications between 2015-2016; more than that spent on dental care and public hospitals combined [5].

Consumers rely on the TGA to guide their treatment choices, which involves both controlling product availability and package labelling, but as consumers are unaware that these package codes exist, or what the codes mean, they are misled by product claims they believe have been substantiated.

Consumers need to be adequately educated and informed about the difference between listed and registered products. This sentiment was reflected in the 2015 Medicines and Medical Devices Review recommendation that prominent disclaimers should be applied to all advertising material relating to listed complementary medicines and state that the efficacy of the claims made for these products has not been independently assessed [6].

Additionally, it is also crucial to strengthen the pre-approval system that examines the claims of listed products *before* they are placed on the market. Doing this will limit the exposure of consumers and patients to products with unsubstantiated claims in the first place.

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A bill to amend the Therapeutic Goods Act, the legislation that guides the TGA, was put forward in Parliament in 2017. The bill proposed to scrap the pre-approval system altogether in favour of shifting towards more "self-regulatory models by industry" and rejected calls to require disclaimers on products that have not been critically appraised [7].

The concern is that this will remove the only, albeit weak, regulatory barrier to publishing erroneous packaging claims. Instead, the system would rely on a post-market surveillance system to discourage bad behaviour. In this system, companies would only be prosecuted after unverifiable claims have been published and purchased, consumers mislead and well after the horse has truly bolted.

With these changes, even greater reliance would be placed on the AUST R/L coding system to inform consumers of the potential merit of product claims; a system which, as discussed, consumers do not understand [5].

Fortunately, after staunch campaigns from consumer advocate groups such as Choice and The Greens, the bill failed to pass the senate, and was sent to a senate committee for review [8-10].

After hearing a range of submissions from consumer advocates to industry representatives, the government reached a compromised amendment, extending the

pre-approval system for another two years with review after 18 months; however, the calls to add disclaimers have not been addressed [7,11].

So the flawed system of regulation is to here to stay, but the proposed changes, that would potentially make this system even worse, have been stopped for now.

It is important for healthcare students and professionals to take notice of these changes to the TGA and understand how the system works. The right of patients to informed choice and consent in their medical treatment is a key ethical pillar that extends outside of the consultation room. This right exists also in pharmacy, where patients are even more vulnerable as they largely rely on the regulators alone to protect their interests and to ensure they are informed.

The debate now moves to the Code Council who is drafting a new Therapeutic Goods Advertising Code. Submissions closed on 27th April 2018 [12]. Let's hope that consumer groups continue to advocate on behalf of the public and our patients and that healthcare groups do more to take notice.

Amy Vaux is a fourth year undergraduate medical student with Monash University. She has been studying the regulation of therapeutic goods and services with Monash University's School of Public Health as a part of a summer research program under the supervision of Associate Professor Ken Harvey.

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