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TGA Transparency Review

MIMS Australia welcomes the opportunity to contribute to the Review to improve transparency of the Therapeutic Goods Administration (TGA).

MIMS collates information from various sources, both locally and overseas, and publishes it in an easy-to-use format for Australian healthcare professionals. One of the prime sources of this information is the TGA for product information (PI). For the most part this information is current and addresses the needs of the healthcare professionals when making decisions around medication therapy. However, there are some deficiencies in the current methodology of ensuring PI content, registered with the TGA, is kept up-to-date.

Orphan Drugs

There are a number of instances where drugs become 'orphaned' e.g. where a discoverer of a new drug cannot afford the high cost of submitting the drug to the TGA for approval or when a drug comes off patent and can be marketed as generic drugs. In the former example, the enactment of Orphan Drug legislation has allowed the use of these drugs under specialist care. In the latter example, the product information at the time the patent expired remains part of the TGA suite of product information and therefore freely available. These drugs may then be manufactured and supplied by generic manufacturers.

Generic manufacturers must submit evidence of the bio-equivalence of their version with the original patented drug, but may rely upon the Product Information submitted and approved for the original drug without having to conduct their own clinical trials. All drug manufacturers must monitor and report adverse events and other pharmaco-vigilance outcomes. Any change to the registered Product Information must be funded by the sponsoring company on the same basis as new drug applications. As there is no incentive for a sponsoring company whose patent has expired to fund this costly exercise, the PI remains in its original state.

MIMS would like to see the TGA find a suitable way to ensure that, for product information for drugs where the patent has expired and the information is old, the PI is updated and reviewed regularly.

ARTG

All medicines manufactured for supply in Australia must be listed or registered in the ARTG, unless they are specifically exempt or excluded.

Assessment criteria

Whether a product is listed or registered in the ARTG depends largely on three things:

- the ingredients;
- the dosage form of the product; and,

- the promotional or therapeutic claims made for the product.

In assessing the level of 'risk', factors such as the strength of a product, side effects, potential harm through prolonged use, toxicity, and the seriousness of the medical condition for which the product is intended to be used are taken into account.[1]

The TGA states that the degree of assessment for **registered products** is 'rigorous and detailed, with sponsors being required to provide comprehensive safety, quality and efficacy data'[2] however, **listed products** 'are considered to be of lower risk than registered medicines, so the Regulations allow sponsors to 'self assess' their products in some situations. The majority of listed medicines are self-selected by consumers and used for self-treatment'[3].

It has been recently bought to the attention of MIMS that many healthcare professionals are not familiar with the differences between a registered and a listed drug. Whilst MIMS can assist to some extent with this issue by making the TGA assessment more obvious to its customers, we believe that the TGA needs to address this issue in the transparency review to ensure that both health professionals and consumers are aware of the limits of assessment with listed products.

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[1] http://www.tga.gov.au/docs/html/medregs.htm#tgact
[2] ibid
[3] ibid