The Pharmacy Guild of Australia

13 June 2013

Comments by the Pharmacy Guild of Australia on Evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods

Background

The Pharmacy Guild of Australia (Guild) welcomes the opportunity to comment on the public consultation paper 'Evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods', prepared by the TGA.

The Guild is an employers' 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.

The Guild works closely with the TGA on many matters, and represents community pharmacy on a number of committees and panels. In addition, the Guild is an active participant in reviews and consultations on regulatory matters for therapeutic goods that relate to community pharmacy practice, providing submissions when appropriate and participating in relevant workshops and forums.

Comments

The following comments relate specifically to matters raised within the Consultation Paper of relevance to community pharmacy.

Whether or not you support the idea of a new-to-market risk communication scheme

The Guild supports in-principle the concept of a new-to-market risk communication scheme.

The potential value and uses of a new-to-market risk communication scheme

The scheme, if implemented appropriately has the potential to better identify and improve reportage of adverse medicine reactions as well enhancing the Quality Use of Medicines (QUM). The scheme also has the potential to improve the health literacy of the general population.

How a new-to-market risk communication scheme might best be designed, promoted and evaluated

Design

The United Kingdom's Black Triangle Scheme seems to be a reasonable model to base an Australian new-to-market risk communication scheme.

Promotion

The Guild agrees that the public may have erroneous perceptions of new-to-market medicines, namely:

- They will always provide a benefit over existing products, or
- They pose a greater safety risk and thus should be avoided

These perceptions could be exacerbated by a poorly directed communication campaign.

To alleviate these concerns, the Guild suggests specific communication schemes should be tailored to health professionals and the general public:

- Communications directed at the general public, should focus purely on promoting awareness, rather than specific details of the scheme (e.g. the risk profile of the medicines). The scheme could focus on the symbol (e.g. black triangle) and simply outline to consumers that these products are new to market. It could operate in a similar fashion to the Australian-made symbol campaign.[i] The communication scheme should emphasise to consumers the need to consult with a health professional (pharmacist, doctor etc) before taking any new products or switching from existing products.
- Any component of the scheme directed at health professionals can focus more on the details of the scheme, what the symbol indicates about the medicine and how they should discuss these issues with patients.

If the aim of the scheme is to encourage health professionals and the public to submit reports to the TGA about adverse events associated with new products, then the reporting process must be simple, transparent, timely, efficient and well communicated.

Currently, navigating to the correct adverse reporting page via the TGA website can be a challenge. The online reporting form can be difficult to follow, particularly for the less health literate. First and foremost, a communication campaign needs to make consumers aware of the relevant contact points to report adverse events for a product and the circumstances in which it would be appropriate. This information could also be presented as labels on new-to-market products. The process also needs to be made simpler, clearer and less onerous, particularly for consumers as well as health professionals.

Evaluation

Evaluation could be determined by conducting surveys of consumers and health professionals to gauge their awareness of the new-to-market risk communication scheme and what effects it had on their knowledge, attitudes and behaviour.

The rate of adverse medicine reporting events for these products would also provide a useful insight into the effectiveness of the scheme.

How a new-to-market risk communication scheme will impact on you. That is what do you see as the likely benefits or costs to you (these may be financial, or non-financial).

As previously stated, the Guild believes the scheme has the potential to improve the health literacy of the general population and enhance the QUM if implemented in partnership with the pharmacy profession.

In terms of cost, it would be expected that time and resources will need to be dedicated to training pharmacists and pharmacy assistants about the scheme so they in-turn can inform consumers regarding the use of new-to-market medicines and specific risks that may be associated with individual products.

As noted in the consultation, one potential mechanism to communicate to health professionals is prescribing and dispensing software. While the Guild would be open to this approach, we would need to be consulted regarding the specifics, as there will be flow-on effects and implications on pharmacy workflow. The electronic flagging of an item being dispensed as 'new-to-market', would be of assistance to pharmacists as a reminder to ensure an explanation to the consumer is included in the counselling process. Consideration will need to be given as to how long a 'new-to-market' classification would apply to a particular product and this would need to be reflected in the dispense system. Software vendors would thus need to be consulted to ensure updates to the 'new-to-market' status of products flow through the system in a timely manner. Consequently, business and cost implications for both pharmacy and software vendors would need to be considered in more depth, if this avenue of communication is pursued.

The other potential benefit of utilising dispensing systems as a form of communication is that this could provide an electronic platform to then link-in to adverse event reporting, as patient details and other relevant information (e.g. other medication) would be readily available electronically via the dispense system.

Pharmacists are often an underutilised component of the healthcare system and are an ideal point of contact for patients who believe they have experienced an adverse drug event. However, pharmacists do not receive a fee for a consultation leading to the reporting of an adverse event on behalf of a patient, unlike a General Practitioner who will receive a payment under the MBS as standard remuneration for a consultation. Consideration should be given to arrange a fee for pharmacists to provide such a service which would improve the reporting of adverse medicine events.

Additional Comments

The Guild notes that communication to health professionals and consumers about the scheme may come in the form of promotional and educational materials produced by the sponsor. While this is reasonable, precautions need to be put in place to ensure this material is not used by sponsors as a tool to bypass restrictions on advertising, in particular Pharmacist-Only medicines not included in Appendix H.

Conclusion

In summary, the Guild supports in-principle a new-to-market risk communication scheme and believes the United Kingdom's Black Triangle Scheme is a reasonable model on which to base an Australian scheme. Information communicated to the public should be limited to general information about the scheme (e.g. developing symbol awareness), and more detailed information should be directed towards health professionals. If the scheme is designed to enhance the reporting of adverse drug events then the reporting process must become simpler and be better communicated.

We therefore consider that the development and implementation of a new-to-market risk communication scheme for therapeutic goods provides an ideal opportunity to review and improve current adverse event reporting processes.

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References

[i] http://www.australianmade.com.au/why-buy-australian-made/about-the-logo/