The Pharmacy Guild of Australia

Comments by the Pharmacy Guild of Australia on

The Discussion Paper for Reforms in the Medical Devices Regulatory Framework – 17 December 2010

Background

The Pharmacy Guild of Australia (Guild) is pleased to be able to provide comment to the Therapeutic Goods Administration (TGA) on the October 2010 Discussion Paper for Reforms in the Medical Devices Regulatory Framework (Discussion Paper).

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.

Community pharmacy is a valuable part of the nation's health infrastructure, from which many medical devices are available to the public, primarily for consumer self-use. Community pharmacies sell products such as medicine measures, measuring meters such as thermometers, blood pressure or blood glucose meters, first-aid supplies, contraceptive devices, non-medicated eye and ear products, dental products and patient aids. The range of devices available is extensive, from low risk dressing strips (Class 1) to condoms and contact lens solutions (Class 11b) and contraceptive intrauterine devices (Class 111). With such a diverse range of devices for sale to the public, it is important that community pharmacy is considered in how it remains informed about regulations that apply to medical devices and how it may support the public.

Comments

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

1. **Proposal 2C – Recognition of third party assessment bodies**
   The Guild supports in-principle, the recognition of third party assessment bodies. We note and support the increased collaboration between the TGA and overseas

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regulatory bodies which have similar standards to Australia with rigorous assessment processes.

Utilising assessments for therapeutic devices from such countries or recognising Australian third party assessment bodies would contribute to improving the efficiency and increasing the capacity in managing device applications, which would be of significant benefit to sponsors, as well as consumers and health care professionals in many cases. However, as identified in the Discussion Paper, it will be important that such arrangements continue to meet rigorous standards, particularly for those devices from higher-risk categories. In particular, we note that the Discussion Paper identifies the need for the TGA to have confidence in certificates issued by third party assessment bodies, whether overseas or Australian bodies. This is essential, for in turn, the Australian public and health care providers rely on TGA processes to ensure therapeutic products meet the expected safety and quality standards.

The Guild supports the proposal that TGA certification for devices classified as higher-risk be mandated, noting that this does not preclude the TGA from capitalising on rigorous assessments performed by overseas regulatory bodies. We also believe that the TGA should have the flexibility to implement similar requirements at their discretion for devices classified as lower-risk if situations warrant such assessment. However, arrangements should be in place to ensure transparency and openness for such decisions.

2. Proposal 3 – Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices

The Guild supports this proposal to improve the useability of the Australian Register for Therapeutic Goods (ARTG).

The Guild would very much like to see an improved search function of the ARTG for both devices and medicines. Whilst there is reasonable scope with the current search function, it is not intuitive. Unless one is familiar with the register's current functionality, it is not user friendly and quite difficult to manage for intermittent or novice users. This is particularly an issue if the aim is to promote greater awareness and use of the ARTG by health care professionals and consumers.

With regards specifically to devices, we would like to see more distinct categories for the ARTG's Public Summary that is standardised for each product, such as:

- ARTG Number
- Device/product type
- Brand name
- Model number/s
- Classification level
- Australian sponsor and contact details
- Registration standing (whether registered, listed or exempt)
- Status (whether active or obsolete)

With standardised, distinct categories, there is then the opportunity to expand the search functionality of the ARTG to allow advanced search options of one or more categories at the one time.

There appears to be some inconsistency on how current ARTG entries are completed, with some containing all information under product details and others breaking down the information into more distinct categories. In addition, the current ARTG search function for devices includes 'active ingredient', which is not appropriate terminology for devices.

The Guild believes that maintaining entries on the ARTG should be a shared responsibility between sponsors and the TGA. Sponsors should have the responsibility of providing the correct information in the appropriate format for initial uptake onto the ARTG. There should then be streamlined processes to facilitate sponsors to maintain and update this information, with the TGA having a monitoring role to ensure currency of information.

With regards to proposal 3(ii) for enhancing the identification of approved devices, the Guild supports including the ARTG number on either the product label or packaging for medical devices if it can be of use to either the consumer or health care professional. Complementing this, we would like to also see a campaign to increase awareness of consumers and health care professionals on what the ARTG number means and how information about the device can be accessed.

We note that in the proposal, it is also suggested that the ARTG number could alternatively be included on the instructions for the device. We would support this as an additional recommendation rather than as an alternative, as we believe there is a greater risk for consumers or providers to lose or misplace instructions, particularly if they are loose sheets. It is also easier for consumers and retailers of devices to access information on the outer packaging if necessary. This could also be of assistance with recalls or safety alerts for any medical devices.

3. **Proposal 4 – Publication of device product information on the TGA Website**
The Guild is very familiar with the information materials available for medicines in Australia and supports the concept of having available information sheets for medical devices that can be readily accessed by either health care professionals or consumers. We would like to see information sheets available for all medical devices, including those classified as lower risk, however, such information must be of use to either a consumer or a health care professional, and the preparation and maintenance of the information sheets should not be onerous. The Guild considers the following would be of relevance for inclusion on publicly available information, the first six replicating proposed information from the ARTG Public Summary:
    - ARTG Number
    - Device/product type
    - Brand Name
    - Model Number/s
    - Classification level
    - Australian sponsor and contact details
    - Information about correct use
    - Information about maintenance (where relevant)
    - Information about separate parts or consumables (where relevant)

Whilst acknowledging that the format of Consumer Medicines Information (CMI) and Product Information (PI) for medicines may at times be criticised and there are

varying opinions as to what should and should not be included, overall, the process of accessing CMIs and PIs has become much more streamlined and efficient. Should information for devices become mandatory, the Guild would support similar arrangements for its preparation and distribution to ensure consistency in access.

4. **General Comment**

We believe that apart from a basic understanding, consumers and many health care professionals, including community pharmacists, are largely unfamiliar with the operations of the TGA and regulations relating to medicines and medical devices. We also doubt that many would be familiar with resources available to them to access information, such as the ARTG, or be confident in its use.

The Guild would support a campaign for training health care professionals and consumers about TGA operations and related regulatory matters and resources. We would welcome the opportunity to discuss this matter further with the TGA, and particularly, how we may be able to assist in directing training specifically to pharmacists to improve their knowledge and understanding of these matters. Having easy access and the public's trust and respect, community pharmacists are well placed to support consumers in accessing information about medical devices when the need arises. An initial investment in training pharmacists could have significant community benefits.

Conclusion

The Guild is pleased with the more transparent and efficient processes espoused within this consultation paper. We support facilitating access of health care professionals and consumers to relevant and greater information about medical devices, and support in-principle, streamlining processes to improve the capacity and efficiency of the TGA in managing applications and assessments. However, arrangements must be adequate so that health care professionals and the Australian public continue to have confidence that therapeutic products available in Australia meet expected high quality and standards.

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