AusBiotech response to the TGA discussion paper regarding Updating of the Uniform Recall Procedure for Therapeutic Goods (Version 1.0, March 2015)

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AusBiotech is pleased to provide input into the TGA's discussion paper regarding 'Updating of the Uniform Recall Procedure for Therapeutic Goods' (URPTG).

AusBiotech would like to commend the work of the TGA and its efforts to work with industry to reform and improve its service. It is to be congratulated for its achievements in recent times, where it has been seeking and enacting continuous improvement via consultation with stakeholders.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes bio-therapeutics, medical technology (devices and diagnostics), food technology, industrial and agricultural biotechnology sectors. Within AusBiotech, the medical device and diagnostic industries are represented by AusMedtech, a special interest industry group dedicated to the development, growth and prosperity of the Australian medical technology industry.

General Comments

AusBiotech welcomes the URPTG discussion paper and its objective to improve the communication of recall actions across all jurisdictions, industry wholesalers and retailers. Clear and consistent communication of recall messages is vitally important to the Australian medical technology industry and AusBiotech supports measures that will improve these processes.

In general AusBiotech agrees with the recommendations in the URPTG discussion paper. The industry's members believe that the recommendations will improve consistency of communication from the TGA. AusBiotech cautions the TGA to ensure it retains the right to handle sensitive information in an appropriate manner. By way of example, this may involve withholding information from time to time that could be commercially sensitive, or aligning the timing of responses with other regulators or jurisdictions when appropriate. The TGA is a world-class regulator and it is important that it retains its independence and license to act accordingly.

Specific comments

Recommendation 1: The URPTG be updated to allow the sponsor's customer letter to be available through SARA.

AusBiotech agrees in general with the TGA response to the blueprint, however, consideration should be given to:

- Allow the Sponsor/Manufacturer to request that the notification/letter not be made public through SARA due to confidentiality issues. In some instances correspondence can include sensitive information, such as investigation details.
- The timing of publication on SARA should be coordinated closely with the Sponsor. Often the letter that is approved by the TGA requires further review internally by medical and safety subject matter experts, which may result in further changes. In addition to this, the TGA sends out the notification/letter to hospitals etc. prior to it being sent to the Sponsor's field staff, which can create confusion.

Recommendation 2: The URPTG be updated to ensure all product sectors and their current regulatory requirements are adequately covered.

AusBiotech supports Recommendation 2.

Recommendation 3: The URPTG be updated to include information on the procedures and processes for recall of biologicals.

AusBiotech supports Recommendation 3.

The TGA should consider reviewing the content and timing of communication with the sponsor that they will initiate during a recall activity. Any recall activity is the responsibility of the sponsor with TGA oversight, therefore the sponsor needs to consider the execution strategy and what potential questions and action may arise and be required from affected parties in the recall execution. If the sponsor is not aware of the content and timing of communications being distributed by the TGA, it can make managing the recall action more difficult for the sponsor and more confusing for customers or affected parties.

When the TGA issues an approved recall notice to a sponsor it would helpful if they also attached copies of the corresponding communication, the intended recipients, and the time line for this communication to be sent. It is important that both parties (TGA and Sponsor) are seen to be in alignment on the issues and know what actions each other are taking. Minimising the risk of miscommunication or confusion of the process should help to ensure the best outcome for affected parties and the general community.

Recommendation 4: The URPTG be updated to remove reference to the Trade Practices Act 1974 and include references to the Competition and Consumer Act 2010.

AusBiotech supports Recommendation 4.

Recommendation 5: The URPTG be updated to remind sponsors that where they supply therapeutic goods that are also 'consumer goods' they have certain obligations under the ACL.

AusBiotech supports Recommendation 5.

Recommendation 6: A mechanism is developed that ensures timely information is being provided to private hospitals through private hospital associations such as the Australian Private Hospital Association and the Catholic Hospital Association.

See comment on Recommendation 6.

Recommendation 7: The TGA review the list of stakeholder organisations in Appendix 5 of the current URPTG to ensure that it is comprehensive.

Updating the URPTG contact list to include the additional stakeholders included in Recommendations 6 and 7 is a positive step forward. To further improve distribution the URPTG appendices should include international stakeholders such as other regulators. Such notifications can be picked up by other agencies, where additional queries and questions are raised. If these additional stakeholders can be made available in the first instance, then a manufacturer/sponsor may take a proactive step to notify other agencies.

The updated URPTG processes should include that notifications to stakeholders will be distributed in an agreed time frame between the sponsor and the regulator. It is not uncommon for recalls to affect more than one regulator/country in which early distribution by a single agency can inadvertently be communicated to another regulator prior to all communications being ready. This can cause notification to any specific regulator to be held off until all jurisdictions are available. Consideration should be taken into account when drafting the URPTG to minimise delays that could have been avoided by clearly communicated notification procedures.

Recommendation 8: The URPTG be updated to explicitly state that the recall procedures and processes in the URPTG also apply to mandatory recalls.

AusBiotech supports Recommendation 8.

Recommendation 9: In order to provide a clear message to market and consistency between Australia and New Zealand, the TGA introduce the new terms 'Health Professional Level' and 'Product Alert'.

AusBiotech supports Recommendation 9 in principle, however, as Medsafe is currently reviewing its recall procedure – it is a difficult comparison to make at this time.

Recommendation 10: In order to provide a clear message to stakeholders, the term 'Product Correction' should be included in the URPTG.

AusBiotech supports Recommendation 10. AusMedtech members report that confusion has resulted from the use of the word 'recall' when product is not necessarily being physically recalled from the field for a product correction.

Additional Recommendation for consideration: Remove the mandatory requirement to send a letter in addition to a fax or email of the Co-ordinator's agreement as stated in Section G of the URPTG.

Section G of the current URPTG states that:

> *"The letter, which may be sent by mail or facsimile or e-mail (and then also posted if sent by facsimile or e-mail), should be despatched within 48 hours of receiving the Co-ordinator's agreement."*

Industry members report that the mandatory requirement to subsequently post letters if sent by facsimile or e-mail creates extra work for both industry and the Department for little benefit and in fact can lead to confusion. Posting a letter should remain an option but should not be required if contact has already been made via email or facsimile.

Considerations:

- The Sponsor/Manufacturer must keep a stock of the special envelopes on hand at all times. Delays can be seen when Sponsors/Manufacturers cannot quickly source envelopes.
- The letters are required to be addressed to 'Chief Pharmacist' or 'Chief Executive Officer' or 'Senior Scientist and/or Pathologist' etc. and in many cases do not reach the personnel using the product under recall in a timely manner.
    - This can result in multiple communications to the Sponsor/Manufacturer from different levels within the one impacted organisation.
    - Users are notified by the Sponsor/Manufacturer via e-mail and after a few days, once the letter is received by the CEO, can be notified again from within their own organisation, leading to confusion (e.g. Does the notice relate to the same recall or a new recall?).
- E-mails can more quickly and efficiently be disseminated to multiple contacts within an impacted organisation - user, goods receipt officers, store keepers, etc. - to ensure efficient and effective quarantining of affected product.

Additional Recommendation for consideration: Clearly define 'Recovery' in the URPTG.

Industry members have suggested that the URPTG is unclear about when the term 'Recovery' should be used. Clear guidance should be considered to minimise confusion.