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Comments on the proposed changes to regulatory requirements for hospital, household and commercial grade disinfectant products.

I am a current member of the Association of Therapeutic Goods Consultants and was also an industry member of the working party that established TGO 54, and prepared the stability guidelines for disinfectants and sterilants as part of the Guidelines for Disinfectants and Sterilants within TGO 54.

I am submitting these comments in my capacity as a regulatory consultant to companies that manufacture and register disinfectants for use in Australia. I have been involved in providing regulatory advice and preparing and submitting registrations for both listed and registered hospital grade disinfectants, and have given expert advice on TGO 54 compliance to organizations that produce both Commercial and Household Grade Disinfectants.

I wish to highlight what I see as concerns and opportunities that arise from the proposed regulatory reform.

Concerns

1. Assurances of efficacy

The current regulation mandates standard tests that could be argued are already aligned to the level of risk of failure. For example Household / Commercial Grade Disinfectants need only pass the TGA Test Option C (two organisms, one challenge), whereas Hospital Grade Disinfectants must pass Option A (in clean conditions) or Option B (in dirty conditions) on four organisms over three challenges. In addition Hospital Grade Disinfectants must also pass a suitable carrier test such as the AOAC Hard Surface Carrier Test. If specific claims are made then additional tests with specific conditions depending upon the organism claimed against must be passed, and these are assessed by the TGA prior to approval being granted.

In the cases of the TGA Tests (Options A, B, and C) and the Carrier Test a minimum 6 $\log_{10}$ reduction in the number of microorganisms is required to demonstrate disinfection.

This allows the product to be marketed as a disinfectant, to use the terms “disinfectant” and “kills germs”.

The current Code of Practice for Antibacterial Products refers only to a 3 $\log_{10}$ reduction in microorganisms, which is significantly less than that required for current Household Grade Disinfectants. Products that meet the Antibacterial Code of Practice will not deliver the same basic disinfectant efficacy against microorganisms as current Household Grade Disinfectants do. The Code of Practice also has no guidelines or protocols for specific claims against specific organisms. I believe there is a concern that the efficacy of products offered to the average household will be compromised without a standard test or tests to maintain a minimum standard of efficacy that the public has come to expect. For an example of this I point to the recent court case between the ASIC and Citrofresh International Pty. Ltd. where proceedings were brought against Citrofresh for making unsubstantiated claims relating to virucidal efficacy.
(see http://www.austlii.edu.au/au/cases/cth/federal_ct/2007/1873.html)

2. Claim proliferation

A concern is that claims will proliferate rapidly as manufacturers look for further opportunities to expand their product range and market share. Without a robust regime of claim substantiation and controls on statements of efficacy, the potential exists for the market to have a multitude of products differentiated by claims for efficacy against non-standard organisms, residual efficacy, increased efficacy, targeted efficacy or high end-use efficacy. Products with claims such as these have already been attempted to be launched on the Australian market. The proliferation of uncontrolled claims will not only create confusion with the consumer but significantly increase the burden on companies operating in the disinfectant category.

3. Definition of a therapeutic good and compliance with therapeutic goods advertising guidelines.

Assuming that the claims made by the “low risk” products will still be classified as being for therapeutic use (as defined in the Therapeutic Goods Act 1989), and these “low risk” products will be regulated by NICNAS, not the TGA, does this change the status of these products with respect to the Therapeutic Goods Advertising Code Council?

4. Shelf life and expiry date determination / substantiation

There are currently well substantiated guidelines for shelf life determination from accelerated stability data that are used to assign shelf life of all disinfectant products. Will these guidelines continue to be relevant and / or enforceable for the “low risk” category of products? How will compliance be monitored and assured?

5. Labelling Requirements

It is unclear whether the current requirements in TGO 54 will be maintained for the “low risk” category products to be regulated by NICNAS, specifically with respect to the declaration of active level and content, and the positioning of this on the label. Similarly the labeling requirements for batch numbers and expiry dates are different between TGO 54 and the Antibacterial Code of Practice. This will need to be resolved.

Will the labelling requirements for the common names listed in TGO 54 still be relevant for the "low risk" category products? Assuming that Hospital Grade Disinfectants will still need to have this common name adjacent to the trade name, what regime will apply to Household, Commercial Grade, and Surface Spray Disinfectant products?

The labelling requirements for products that are subject to other regulatory labelling requirements needs to be considered. For example, what about the heights and colours of warnings, and priorities of various conflicting or overlapping codes such as Poisons Scheduling, Dangerous Goods labelling, and APVMA requirements?

Opportunities

A common frustration amongst the clients I have acted for has been the need to redo various efficacy tests that have already been accepted by overseas regulatory bodies such as the EPA, with different conditions. I see the current reform as an excellent opportunity to review and where possible agree to accept data that already supports registered products in other countries. Some tests mandated within TGO 54 also need reviewing to bring them into line with accepted best practice.

There has been some confusion within industry and lack of clarity in TGO 54 as to what constitutes a therapeutic claim, what constitutes a disinfectant claim, and what words or symbols are allowable as generic claims versus specific claims, especially for listed Hospital Grade Disinfectants and Commercial / Household Grade Disinfectants. The current reform can be used to provide more specific guidance so that sponsors of disinfectant products are clear as to what are permitted representations and what are not permitted.

Summary

As a consultant to key companies that market disinfectants, I see both concerns and opportunities within this regulatory reform proposal.

Whilst in principle I agree to the relieving of regulatory burden both on industry and government, I strongly urge that the new regulatory framework considers all of the above issues to ensure that there is clear and complete guidance for both industry and government. Moving to a new regulatory system without suitable checks, guidelines and controls in place would impose further burden both on industry and the government and create greater confusion to the end user.

Yours Sincerely,

Dr. Paul Wynn-Hatton
28th April 2008