28 April 2008

Ms Siepie Larkin
MDP 122
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Ms Larkin,

RE: Proposed changes to the regulatory requirements for hospital, household and commercial grade disinfectants

Reckitt Benckiser appreciates the opportunity to comment on proposed changes to the regulation of hospital, household and commercial grade disinfectant products.

We market a number of domestic-use products, including disinfectant products, both locally and internationally. The disinfectant products marketed in Australia are regulated by the TGA, and include products with each of the 'status' types – exempt, listable and registrable.

Of the options presented in the consultant's report, we believe that Option 4 is the most appropriate to provide assurance of standards (in particular efficacy) for products with a higher public health risk.

Option 4 – compliance with *"hospital grade" definition and/or presence of 'specific claims' on label provide point of demarcation, i.e.*

- **All disinfectant products labelled as 'hospital grade', and all commercial and household grade disinfectant products carrying specific biocidal claims, will be classified as therapeutic devices and be required to be listed on the ARTG**
- **All commercial and household grade disinfectants (except those labelled as 'hospital grade') without specific biocidal claims, antibacterial cleaning wipes; and sanitisers, cleaners and deodorisers, will be regulated by NICNAS.**

Clinical settings and settings involving the penetration of human skin are situations with a higher public health risk, and there is a potential higher public health risk associated with 'specific' organisms. Option 4 also retains the hospital grade claim with its associated standards (efficacy standards, TGA oversight), and avoids confusion about the term 'hospital grade' and the potential loss of the meaning of 'hospital grade' which would result from the changes proposed in Options 2 and 3.

Comments on Recommendations

Recommendation 1

We believe that the change to the definition of hospital grade disinfectant is acceptable, even though some commercial premises such as beauty therapy and podiatry practices may carry out procedures involving penetration of human skin, e.g. body piercing.

Recommendation 2

We support the proposed division of the regulation of products based on their risk. However, we believe that the Option 4 demarcation better addresses the risks presented by the manufacturer's intended use for the disinfectant, as discussed previously in these comments.

Recommendation 3

As stated above, we submit that Option 4 better addresses the risks associated with the intended use of hospital and household/commercial grade disinfectants, antibacterial cleaning wipes and sanitisers, cleaners and deodorisers.

Recommendation 4

We agree that duplication of assessment should be avoided, and hence support this recommendation.

Recommendation 5

We do not have a particular view on this recommendation.

Other Comments

Maintenance of standards: The current TGO 54 efficacy standards provide a suitable standard for performance, and it is very important that efficacy standards for disinfectant products are not lowered. We believe that consumers have a right to expect that the efficacy standards for disinfectants are maintained; they should be able to be confident that current performance will not be adversely affected by the proposed changes to regulation.

Where other internationally-accepted standards offer equivalent or better performance than our current standards, we believe that these should be acceptable alternatives to the TGO 54 protocols.

International best practice: Both the US and EU have product-based systems for the regulation of the types of disinfectant products under discussion in these proposals. The EU is fully implementing their product-based system over the next few years. Antimicrobial performance assessment is included in these systems. Australia will be **moving away from** the practice in major western economies by changing from product-based to chemical-based regulation. We also believe that it

will be easier to move towards harmonising with major economies under a product-based system of regulation.

'Hospital grade' disinfectants: Disinfectants labelled 'hospital grade' should continue to be available for use by domestic consumers, as proposed in the report. Householders currently have access to these higher performance products and this access should be retained.

Good Manufacturing Practice: The report recommends that GMP is not necessary for these disinfectant products, and we agree with this. Internationally, GMP is not a requirement for these types of disinfectants.

Transitional arrangements: Any changes to current arrangements will require appropriate transitional arrangements and an adequate transition period. Impacts of the changes on labelling, data requirements, reformulation etc, are as yet unknown, but industry will need adequate time to make any required changes in a manner which minimises the cost as well as allows the necessary resources to be available to handle the workload.

We are pleased to submit these comments for your consideration. If you have any questions, please contact the undersigned.

Yours sincerely

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