



AUSTRALIAN SELF-MEDICATION INDUSTRY
BETTER HEALTH THROUGH RESPONSIBLE SELF-CARE

28 April 2008

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

Email: siepie.larkin@health.gov.au and stephen.zaluzny@nicnas.gov.au

Dear Ms Larkin,

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

ASMI members have reviewed the proposed changes to the regulatory requirements for hospital, household and commercial grade disinfectants and the associated documents and offer the following comments.

Recommendation 1

The rewording of the definition of a 'hospital grade' disinfectant is appropriate.

Recommendation 2

ASMI supports the following conditions of this recommendation:

- The division of products based on the public health risk presented by the manufacturers intended use for the disinfectant
- High risk products remain the jurisdiction of the Therapeutic Goods Administration (TGA).
- Licensing of manufacturers of manufacturers for Good Manufacturing Practice (GMP) should NOT be required for these products.

However, ASMI believes that **Option 4** is the most appropriate regulatory framework to meet the objective of Recommendation 2.

Option 4

- "Hospital Grade" disinfectants, whether carrying specific biocidal claims or not, will be classified as therapeutic devices and be required to be listed on the ARTG
- Commercial and household disinfectants (except products labelled as "hospital grade"), that carry specific biocidal claims will be will be classified as therapeutic devices and be required to be listed on the ARTG.

SUITE 2202, LEVEL 22, 141 WALKER STREET, NORTH SYDNEY NSW 2060
POST OFFICE BOX 764, NORTH SYDNEY NSW 2059
PHONE: +61 2 9922 5111 FAX: +61 2 9959 3693
WEBSITE: WWW.ASMI.COM.AU ABN 55 082 798 952

REPRESENTING THE CONSUMER HEALTHCARE PRODUCTS INDUSTRY FOR OVER 30 YEARS

- Commercial and household disinfectants (except products labelled as “hospital grade”), that do not carry specific biocidal claims, antibacterial cleaning wipes; and sanitisers, cleaners and deodorisers, will be regulated by NICNAS

ASMI believes that products that include ‘specific disease related claims’ should be regulated under the jurisdiction of TGA regardless of whether they also claim ‘hospital grade’ or not. This ensures that these products regulated by the TGA are providing a greater level of assurance of the efficacy of these products for use in potentially high risk applications and also in line with the specific biocidal claims.

Recommendation 3

This recommendation is a restatement of Option 1 under Recommendation 2. ASMI maintains that this should refer to Option 4 as outlined above. The concern arising from the potential for duplication of safety assessment is noted but is not considered to be of significant import.

Recommendation 4

ASMI supports this recommendation.

Recommendation 5

Not considered as important by ASMI members.

General Comments

There was some concern raised over the potential for the efficacy standards for disinfectants to reduce. Currently the requirement to comply with TGO 54, 54A and 54B establishes a level of microbial performance, it is important that efficacy standards are maintained by a continued requirement to meet a minimum standard. This may take the form of equivalent international standards.

ASMI would like to see the continued availability of “hospital grade” disinfectants for household use. Hospital Grade disinfectants provide domestic consumers with the choice of a higher performance product.

The report does not propose GMP for those disinfectants that are to remain under the regulation of the TGA, ASMI agrees that this is appropriate.

Advertising of therapeutic goods is regulated by the Therapeutic Goods Advertising Code (TGAC).

Currently, advertisements for disinfectants, as therapeutic goods, are bound by the TGAC.

Disinfectants that remain under the jurisdiction of the TGA and therefore must comply with the TGAC should not be adversely affected, with regard to advertising, compared to disinfectants that are deemed not to be therapeutic goods and that do not need to comply with the TGAC. ASMI suggests that those disinfectants that fall under the jurisdiction of the TGA be exempt from the requirements of the TGAC.

ASMI is unsure with regard to the commercial implications of getting a new product to market when comparing the two regulatory processes, i.e. cost of a TGA submission vs. the cost of a NICNAS

submission. This may become important when applied to a new active ingredient. It would be appropriate that the relative costs be comparable.

Thank you for the opportunity to provide comment on this proposal. We hope these comments are useful and we look forward to participating further in this ongoing process.

Yours sincerely

A handwritten signature in black ink that reads "Angela Lance." The signature is written in a cursive style and is centered within a light gray rectangular box.

Angela Lance

Regulatory Manager

Australian Self Medication Industry (ASMI)

Suite 2202, Level 22, 141 Walker St, North Sydney NSW 2060

P.O. Box 764, North Sydney NSW 2059

Ph: +61 2 9923 9411

Mob: 0419 128 054

Fax: +61 2 9959 3693

Email: angela@asmi.com.au