Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian Government
Department of Health and Ageing
NICNAS

Dear Stakeholder

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

This is to seek your comment on proposed changes to the regulation of hospital, household and commercial grade disinfectant products as detailed in the attached consultant's report entitled "A new regulatory framework for disinfectants".

In response to a recommendation in the Australian Government's Report of the Taskforce on Reducing Regulatory Burdens on Business (Banks report, January 2006), NICNAS and the TGA engaged Dr Simon Brooke-Taylor to review the current Australian regulatory framework for disinfectant products and review the regulation of disinfectants in comparable overseas countries to assist in identifying best practice models.

The TGA and NICNAS would welcome your comments on the proposals in the report, in particular, the consultant's recommendation 3 as the preferred option for a new regulatory framework for disinfectants in Australia.

NICNAS and the TGA are also seeking information to allow preliminary assessment of the regulatory impact of this proposal, as required under Government best practice regulation policy. Specifically information is sought on potential business compliance costs and impacts on business and individuals, including restrictions on competition. It is therefore requested that the 'business impact checklist' included at the end of this letter also be completed and returned with your comments on this proposal.

In addition, it is proposed to hold stakeholder information sessions, in the fortnight commencing **31 March 2008** to allow further discussion on the regulatory proposal.

Submission of comments

Your comments on the proposed legislative amendments for disinfectants, particularly your advise on whether you support option 1 in the consultants report, as well as comments on possible financial implications for moving to this new model, would be appreciated by cob **28 April 2008** If you have any enquiries about this proposal please contact:

Mr Stephen Zaluzny on phone (02) 8577 8883 or e-mail: stephen.zaluzny@nicnas.gov.au
or
Ms Siepie Larkin on phone: (02) 6232 8721 or email: siepie.larkin@health.gov.au.

Comments may be sent by email to the above addresses, or by mail, and should include your full contact details. The mailing address for comments is:

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

All comments submitted will be placed on the TGA and NICNAS websites and be publicly available.

Stakeholder information sessions

For those interested in attending a stakeholder information session can you please complete the attached 'expression of interest' form and return it by fax to (02) 8577 8888 or by mail to the address on the form by **14 March 2008** information sessions will be held before the close off date for submission of comments. Currently sessions are planned for Sydney and Melbourne, however, if there is sufficient interest in other locations then consideration will be given to holding meetings elsewhere. It is important that the expression of interest form is returned with completed contact details. NICNAS will contact all persons returning the form to advise them of meeting locations and times, details of which will also be advertised in local newspapers and on the TGA and NICNAS web-sites.

All comments made at public information sessions will be placed on the TGA and NICNAS websites and be publicly available.

Yours sincerely

Rita Maclachlan
Director
Office of Devices Blood and Tissues

Dr Marion Healy
Director
NICNAS

February 2008

Enclosures

1. Business impact checklist.

2. Expression of Interest form to attend stakeholder information sessions.

3. A new regulatory framework for disinfectants. Report prepared for NICNAS and TGA by Dr Simon Brooke-Taylor.

4. Guide on proposed changes to regulation of disinfectants

BUSINESS IMPACT CHECKLIST

REGULATORY PROPOSAL: REVISED REGULATORY REQUIREMENTS FOR HOSPITAL, HOUSEHOLD AND COMMERCIAL GRADE DISINFECTANTS

ORGANISATION: .....

1 Please indicate whether any <u>additional</u> compliance costs would result for businesses from the proposal?

Yes ☐ No ☐

2. If yes, and taking into consideration total operating costs, would these <u>additional</u> compliance costs be:

Negligible ☐ < 1.0% ☐ 1-5% ☐ 5-10% ☐ >10% ☐

3. If yes, describe what activities the additional compliance costs would be attributable to:

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4. Do you consider that the proposal would restrict competition?

Would the regulatory proposal affect the number and range of suppliers?

☐ Yes ☐ No

Would the regulatory proposal change the ability of suppliers to compete?

☐ Yes ☐ No