Paragon Therapeutic Technologies Pty Ltd
PO Box 422
Glen Huntly 3163
Victoria Australia
ACN 126461701
T +613 9578 1420
F +613 9578 1415
M +61 (0) 411 713 444 (H Pose)
M +61 (0) 414 774 017 (C Cuthbertson)
M +61 (0) 409 190 248 (B Evers-Buckland)

23 April 2008

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

Dear Seipi

RE: Proposed Changes To The Regulatory Requirements For Hospital, Household And Commercial Grade Disinfectants – Consultation

Paragon Therapeutic Technologies welcomes the opportunity to provide input into the consultation process on hospital, household and commercial grade disinfectants. Paragon Therapeutic Technologies is a consultancy for regulatory and quality compliance in the medical device and allied product industry and has more than 150 clients in the field. Many of our clients are suppliers and manufacturers of various grades of disinfectant.

1. Regulatory Control Of Disinfectants

Currently the regulation of disinfectants falls under the Therapeutic Goods Administration except where the products are exempted. The Australian consumer has an expectation that for hard surface disinfectant products that are used to control infection should be under the remit of the Health Authority and in particular with those who are able to analyse if the product and its claims are satisfactory to strict quality, safety and efficacy criteria.

NICNAS is responsible for the safety of individual chemicals not products and therefore its focus is not related to product safety and efficacy. It is our contention that moving any disinfectant product under the NICNAS umbrella is not a satisfactory proposal.

We were most concerned to hear during the consultation that NICNAS would seek to control the chemicals through the importation of the chemicals. Our clients do not import the chemicals but use importers so the so called anticipated controls are lost.

NICNAS does not oversight the quality of the product sold in the market place. It is inappropriate to rely of Consumer Affairs to take relevant action when there is a problem. It is too late and the public health has therefore been put at potential risk.

A more regulated environment that ensures product and manufacturers are compliant to regulation before product is placed on the market is required. The current Therapeutic Goods Act accommodates this requirement.

We do not support the splitting of disinfectant controls between TGA and NICNAS.

2. Regulation Criteria Of Disinfectants

Our experience in the industry leads us to conclude that a formal approval process should apply to both Hospital Grade and Household/commercial Disinfectants regardless of whether claims are made. The assumption that compliance to TGO54 has been achieved without a formal approval process is not an adequate way to ensure safety and efficacy with these products. Our industrial experience has demonstrated that manufacturers do not undertake the full requirements including the stability studies, end shelf life activities and full testing at release because there are no current controls in place to ensure they undertake the work.

The regulation currently in place for these products is a confused array of documents stemming from the original DR4 and the related Appendix 18.

We would recommend that if the criteria for disinfectants was to remain under the TGA that a separate Therapeutic Goods Order be written for disinfectants that are not medical devices i.e. sterilants etc. and that the guidelines clearly indicate the way in which compliance is to be demonstrated to TGA. Removing all references to sterilants would make the standard more user friendly.

If a standard is required for sterilants then a separate standard (MDSO) should be issued. In other words the standards should be separated to ensure less confusion for compliance.

3. Licensing Standards Of Manufacturer

We disagree with the recommendation that manufacturers of disinfectants should not be licensed. It is time that appropriate manufacturing standards are applied to the manufacture of these products.

Our view is the ISO 13485 standard is appropriate to ensure that process validation, product risk and assessment and quality review and release will be demonstrated. We are of the opinion that an application of the GMP medicine code would be inappropriate for these products as the medicine criteria is not relevant to the product category.

All manufacturers should be licensed by TGA to ensure compliance to ISO 13485 for the manufacture of disinfectants. The licence is not to be a Conformity Assessment process.

4. Definition of Hospital Grade Disinfectant

The current definition for hospital grade disinfectant has been defined as:

"Hospital grade disinfectant means a disinfectant that is suitable for general purpose disinfection of building and fitting surfaces, and purposes not involving instruments or surfaces likely to come into contact with broken skin:

(a) in premises used for:

(i) the investigation or treatment of a disease, ailment or injury; or

(ii) procedures that are carried out involving the penetration of the human skin; or,

(b) in connection with:

(i) the business of beauty therapy or hairdressing; or

(ii) the practice of podiatry;

but does not include :

(a) instrument grade disinfectants; or

(b) sterilant; or

(c) an antibacterial clothes preparation; or

(d) a sanitary fluid; or

(e) a sanitary powder; or

(f) a sanitiser;"

The proposed Hospital grade disinfectant definition:

"**hospital grade disinfectant** means a disinfectant that is suitable for general purpose disinfection of building and fitting surfaces in premises used for:

(i) the investigation or treatment of a disease, ailment or injury; or

(ii) procedures that are carried out involving the penetration of the human skin;

but does not include :

(a) instrument grade disinfectants; or
(b) sterilant; or
(c) an antibacterial clothes preparation; or
(d) a sanitary fluid; or
(e) a sanitary powder; or
(f) a sanitiser; "

We support the new definition as long as any supporting documentation does not imply control of where this level of disinfectant could be marketed. The removal of part (b) of the original definition does not prevent usage in those areas, however the language of the consultant's report appeared to have an alternative agenda for disinfectant controls. If the intention of this definition is therefore to drive a change in where product could be supplied we would argue this lies outside of the remit of the therapeutic goods legislation.

The explanations provided in the consultation document failed to recognize the way in which the term Hospital Grade Disinfectant is used in the market place and the market place expectations. Redefining these expectations will only cause greater confusion to the customer. Customers perceive product carrying Hospital grade claims as a higher quality product and the household grade alternative as a lesser grade and of poorer quality.

We are of the opinion that while there is a preference by legislators to ensure the hospital grade disinfectant is of a defined standard for clinical application it is not a requirement of any current legislation to restrict the actual places of usage and unwise in any explanatory documentation to incorporate such exclusions. **There are alternative mechanisms to ensure these clinical environments use the appropriate grade of disinfectant.** We would therefore discourage both TGA and NICNAS from attempting to dictate to the market through legislation where different grades of disinfectant are to be sold.

Our Recommendations

On reviewing the consultation document presented by TGA and NICNAS we would recommend that :

- Hospital grade and household/commercial grade disinfectants remain as therapeutic goods under the Therapeutic goods Act and are subject to an approval regardless of the grade or whether claims made;
- A separate Therapeutic Goods Order be developed to cover only these products (separate the requirements of the medical device classified disinfectants [e.g. sterilants]) ;
- Manufacturers must have compliance to ISO 13485 with a manufacturing licence to be issued by TGA.

We do not support any proposal that seeks to move disinfectant control to NICNAS as their charter does not allow the individual approval of products and there is a clear need for a formalised process of approval to satisfy the public expectation of quality, safety and efficacy.

We look forward to continuing development of legislation in this area of the medical device industry and would welcome any further discussions or interaction with legislators on this proposal.

Yours sincerely
Paragon Therapeutic Technologies Pty. Ltd.

Christine Cuthbertson
Director

Barry Evers-Buckland
Director

Harry Pose
Director