Medical Technology
Association of Australia

Proposal to change the regulatory requirements for hospital, household and commercial grade disinfectants

Submission by
Medical Technology Association of Australia

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1. About the Medical Technology Association of Australia and the Medical Technology Industry

The Medical Technology Association of Australia (MTAA, formerly Medical Industry Association of Australia) represents the manufacturers, exporters, importers and distributors of medical technology products in Australia. Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability. This also includes companies supplying disinfectants directly or products requiring the application of various grades of disinfectants before use.

The medical technology industry in Australia has an annual turnover of $4.75 billion (2006/2007) and earns an export income of $1.75 billion (2006/2007). It is characterised by a small number of global multinational companies (approximately 20% of the industry) and a large number of small and medium sized enterprises (80% of the industry). The Australian market is small - less than 2% of the global market for medical technologies.

2. Comments on the Proposal

Comments from MTAA members indicate:

(i) Support for the implementation of Recommendation 1

(ii) Support for the implementation of Option 4 of Recommendation 2

However this support is conditional on how the implementation of all options of Recommendation 2 is achieved. As all options in Recommendation 2 move products from TGA to NICNAS control to some degree, if the consequential costs and regulatory burden become too great, companies will not be able to introduce certain products to the Australian market. This may also result in some current products being removed from the Australian market.

In each case, both market competition and the introduction of new technology in healthcare facilities are likely to be restricted in comparison to the current regulatory environment. This will also place Australian healthcare facilities at a distinct disadvantage to overseas facilities which are more easily able to access these types of products. This is then likely to introduce an adverse impact on the competitiveness of Australian based companies when compared with their overseas competitors. It is important, therefore, to minimise the commercial impact of moving products from TGA to NICNAS jurisdiction as much as possible.

(iii) Support for the implementation of Part 1 of Recommendation 3 in conjunction with Option 4 of Recommendation 2.

However, this recommendation can only be appropriately implemented if it is used to augment the implementation of Option 1 of Recommendation 1.

The MTAA does not consider Option 1 in isolation to be the best option available and therefore cannot support the complete implementation of Recommendation 3 without the suggested modification. As a consequence, disinfectants labelled as ‘hospital grade’, regardless of claims, place of use, or other characteristics, would be regulated by the TGA. This would then capture these products within the TGA framework and reflect customer expectation that products advertised for use in hospitals undergo efficacy confirmation.

In supporting the comments from MTAA members, MTAA affirms the need for the TGA to confirm the efficacy for those products for which there is a reasonable assumption that users require it.

The MTAA would welcome discussions with the TGA and NICNAS on ways this proposal would be put into practice and what effect, in practical terms, of the impact it will have on the regulatory work for all therapeuitc goods, as well as information and training programs for the industry from the TGA and

NICNAS before this proposal was put into effect. This is crucial in considering the references to the ANZTPA legislation in the report and public announcements concerning changes to TGO 54.

The MTAA:

- would appreciate additional infomation to be provided by the TGA and NICNAS that confirms this proposal would result in reducing the financial and regulatory impact on companies that would be required to make applications for new chemical entities on the AICS.
- strongly encourages that proposed amendments to the legislation and guidance documents clearly indicate that the proposed changes do not relate to disinfectants that are currently regulated as medical devices. There already appears to be some confusion in interpreting some statements made during the recent public consultation sessions.
- would encourage the use of consistent terminology when describing the products under discussion in this proposal with the use of the term “therapeutic goods”.
- expects that an appropriate transition period be provided if and when legislative changes are introduced.