

Device Technologies Australia Pty Ltd –

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

After close review of the report prepared for NICNAS and the TGA by Dr Simon Brooke-Taylor 'A new regulatory framework for disinfectants' (the Report), Device Technologies Australia, puts forward the following comments and discussion.

1. We support the implementation of Recommendation 1
2. We support the implementation of Option 4 of Recommendation 2
3. We support the implementation of Part 1 of Recommendation 3 *in conjunction* with Option 4 of Recommendation 2
4. We suggest a method of implementation of Recommendation 4 which will aid the implementation of Recommendations 2.

This would result in the below tabulated changes:

Type of Product	Current requirements	Supported Recommendations
		Combined implementation of: 1. New definition of 'Hospital Grade Disinfectant' 2(Option 4). Based on new definition for 'Hospital Grade Disinfectant' and labelled specific or non-specific claims 3(Part 1). Labelled 'hospital grade' disinfectant products to be regulated by the TGA
Sterilant & Instrument Grade Disinfectants	TGA - Class IIb medical device	no change - outside scope of the Report
Detergents & Medical Device Cleaners	TGA - Class I medical device	no change - outside scope of the Report
Hospital Grade Disinfectant - specific claims	TGA - OTG - Registrable	TGA - OTG - Listable
Hospital Grade Disinfectant - non-specific claims	TGA - OTG - Listable	TGA - OTG - Listable
Labelled 'Hospital Grade' Products	Dependant on labelled claims and use	TGA - OTG - Listable
Household/Commercial Grade Disinfectant - specific claims	TGA - OTG - Registrable	TGA - OTG - Listable
Household/Commercial Grade Disinfectant - non-specific claims	TGA - OTG - Exempt from ARTG	NICNAS + codes of conduct
Antibacterial clothes preparation	TGA - OTG - Exempt from ARTG	NICNAS + codes of conduct
Sanitisers	TGA - OTG - Exempt from ARTG	NICNAS + codes of conduct
Sanitary fluids & powders	TGA - OTG - Exempt from ARTG	NICNAS + codes of conduct
	NOTE: All currently need to comply with TGO 54	NOTE: Only TGA regulated products need to comply with TGO 54

Our reasoned assessments, resulting in the support indicated above, are set out on in **Appendix A**. Of major consideration in this assessment was:

- The need to maintain an assessment of efficacy (by the TGA) for those products where it is reasonable to assume there is such a customer expectation.
- The effect on regulators and industry of moving disinfectants from the jurisdiction of the TGA to NICNAS
- Reducing the financial and regulatory impact on companies who would be required to apply for new chemical entities on the AICS.
- Reducing the impact on NICNAS resources for such new assessments.

Additionally, some important observations regarding the Report are:

- There are a number of ways the Report recommendations and options can be interpreted, which can lead to great confusion and difficulty.

To clarify our response comments, we have made use of the most logical and useful interpretations. These are clearly indicated at the beginning of each section in Appendix A as necessary.

- At present all disinfectants regulated by the TGA must comply with TGO 54. The Report indicates that TGO 54 will be replaced by an ANZTPA document.

As ANZTPA is no longer going ahead, it is important for industry to be advised of current status of proposed changes to TGO 54. This will impact the regulatory burden on any products that remain under TGA jurisdiction and needs to be taken into account when implementing changes to disinfectant regulation.

At the information session in Sydney on the 1st of April, 2008, TGA representatives indicated that TGO 54 was being revised to include a higher level of toxicity testing/requirements and that the document may well be split into two to reflect separate requirements for disinfectants that are Medical Devices and disinfectants that are Other Therapeutic Goods. It would be beneficial for further consultation to be conducted on this topic.

- The Report consistently uses conflicting terminology:

i. Use of the term ‘therapeutic device’ to describe disinfectants

In current legislation, the definition of the term *Therapeutic Device* refers to ‘*therapeutic goods ... which does not achieve its principal intended action by ... chemical ... means...*’. Therefore, the correct terminology for disinfectants is that they are ‘therapeutic goods’. Using the term ‘therapeutic device’ for these products causes confusion as devices are regulated by medical device legislation. Refer to **Appendix D** for complete definition and source.

ii. References to registration of disinfectants as medical devices

It is noted that the flowchart in Appendix 4 of the Report refers to application to the ‘*TGA for listing of product on the ARTG as a medical device*’. This was discussed at the information session and recognised as a mistake. It is suggested that this should instead read ‘*...as a therapeutic good*’.

iii. Statements referring to ‘all disinfectants’

We strongly suggest that any legislation and guidance documentation developed very clearly indicates that the changes do not in any way relate to disinfectants that are medical devices. For example, statements have been made in the consultation documents and the TGA information session with respect to ‘all disinfectants’. This causes extreme confusion and if use of such terminology continues into legislation the regulatory burden would be extreme on those disinfectants that are medical devices.

It is suggested that these inconsistencies are addressed and clarified in the next set of documentation released by NICNAS and the TGA regarding disinfectant legislation.

FURTHER DISCUSSION

There is a major disadvantage across the implementation of all options of Recommendation 2. All options in Recommendation 2 move products from TGA to NICNAS jurisdiction to some degree.

If the costs and regulatory burden (associated with including chemical entities for these products on the AICS) is too great, companies will not be able to introduce certain products to the Australian market.

Similarly, this may result in the removal of current products from the Australian market.

In each case, both market competition and the introduction of new technology in healthcare facilities will be greatly 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.

In order to avoid this, it is important to reduce the commercial impact of moving products from TGA to NICNAS jurisdiction as much as possible.

Therefore, our support of the items as presented on page 1 (especially the implementation of Option 4 of Recommendation 2) is because this combination moves the least amount of products from TGA to NICNAS jurisdiction and also meets customer expectations that ‘hospital grade’ products and those with high level claims are assessed for efficacy.

Additionally, introducing a scheme as we suggest in Recommendation 4 (see Appendix A) would greatly assist in reducing such commercial impact, as well as reducing the impact on regulators resources for assessment of new chemical entities.

It is also very important that the level of assessment by the TGA is reduced from Registered to Listed for ALL non-medical device disinfectant products, as initially proposed in the ‘*Summary of regulation of disinfectants and sterilants*’, released in July 2005 (See **Appendix C**)

APPENDIX A

Reasoned Assessment of the Recommendations

1. RECOMMENDATION 1

A change in the current definition of *hospital grade disinfectant* to remove the references to commercial premises (shown below) is supported.

(b) in connection with:

- (i) the business of beauty therapy or hairdressing; or
- (ii) the practice of podiatry;

Such a change will better reflect the intention of the definition to capture products used in hospitals and other clinical settings.

2. RECOMMENDATION 2

It is recognised that the matters in this section are complex, however, in order to aid the comparison of the options an accompanying table would have been of great assistance. We have created and included such a table in **Appendix B**.

During the information session held by NICNAS and the TGA in Sydney on the 1st of April, 2008, comments were encouraged to include positive and negative impacts as well as to whom this impact affected. This is the approach followed below for each option.

As there are also a number of ways that Options 1-4 can be interpreted, our interpretations are clearly indicated at the beginning of section. These represent the most logical and useful interpretations of the recommendations presented in the Report.

OPTION 1

Interpretation:

This approach makes use of the revised definition of *hospital grade disinfectant*, effectively meaning that:

- *Hospital grade disinfectants* are regulated by TGA.
- All other disinfectants (excluding medical device disinfectants) are regulated by NICNAS.

Advantages

For Consumers: Maintains customer expectation and understanding that 'hospital grade disinfectants' are assessed according to efficacy.

For All: Easy identification of products that belong in each group.

Disadvantages

For Customers: Household/commercial disinfectants with high level (specific) efficacy claims are not assessed.

For Industry: Excessive financial and regulatory burden placed on importers/manufacturers of household/commercial grade products that have previously not required entry of all chemical entities on AICS. (This would also apply to antibacterial clothes preparations, sanitisers, etc) *See **Note 1** for further comments.

For Regulators: Large increase in number of assessments for chemical entities on the AICS. Government resources will be under strain.

For All: Labelled 'hospital grade products' are not included, and therefore customer expectation that these products undergo efficacy testing is not met. *Note: The implementation of Part 1 of Recommendation 3 would solve this issue.*

OPTION 2

Interpretation:

This approach is based on the labelled claims made (i.e. *specific* and *non-specific*, as currently defined in the Guidelines to TGO 54), effectively meaning that:

- Disinfectants with *specific claims* are regulated by TGA.
- Disinfectants with *non-specific claims* are regulated by NICNAS.

Advantages

For Consumers: All products claiming to have effectiveness against high level risks (e.g. viruses) will be assessed for efficacy. Hospitals will not be able to use a *commercial grade disinfectant* that has these specific claims without it having been assessed for efficacy.

For Industry: Reflects the current standard of assessment for products with specific claims. All competitors that want to make specific claims will be subject to the same controls regardless of the product application. The manufacturer would still be required to maintain records to the same level as is currently required for products with specific claims.

Disadvantages

For All: Recommendations 1 and 3 become redundant. The definition and labelling of *hospital grade disinfectant* would not be used in any meaningful way. Labelled 'hospital grade products' are not included.

For Consumers: The current understanding that hospital grade disinfectants undergo assessment for efficacy would no longer be true. This would increase the degree of confusion due to a significant change in terminology.

For Industry: Movement of disinfectants with *non-specific claims* to the jurisdiction of NICNAS instead of the TGA would introduce an unnecessary level of regulatory burden. *See **Note 1** for further comments.

For Regulators: Large increase in number of assessments for chemical entities. Government resources will be under strain.

OPTION 3

Interpretation:

This approach is based on where the product is used:

- Products used in a clinical setting (*suggested to include hospitals, general practice, day surgery centres, domiciliary nursing services, residential aged care, community services or office practices such as dentistry or podiatry*) regulated by the TGA.
- Products not used in a clinical setting regulated by NICNAS.

Advantages

For Consumers: All products used in a clinical setting would be assessed for efficacy.

Disadvantages

For All: A definition of clinical setting has not been established in this industry sector, so there is great potential to cause and increase confusion amongst all parties regarding which products are (customers) or need to be assessed (industry and regulators) for efficacy.

For All: Recommendations 1 and 3 become redundant. The definition and labelling of *hospital grade disinfectant* would not be used in any meaningful way and the inclusion of podiatry practices contradicts the intention of Recommendation 1. Labelled ‘hospital grade products’ are not included.

For Consumers: The current understanding that hospital grade disinfectants undergo assessment for efficacy would no longer be true. This would increase the degree of confusion due to a significant change in terminology.

For Regulators: This distinction would be very difficult to regulate as it is not always straightforward to predict the products customers in hospitals and ‘clinical settings’ choose to use.

For Industry: Special labelling for the Australian market may have to be developed to include reference to a ‘clinical setting’ definition.

For Industry and Regulators: Potentially, a large number of products would move from TGA to NICNAS jurisdiction. *See Note 1 for further comments.

This would also be very unpredictable and dependant on the confirmed definition of a clinical setting, but may lead to unnecessary regulatory burden on industry and strain of regulator resources.

The regulatory impact on industry is unpredictable as such a distinction has never been the focus for disinfectants.

Furthermore, the revised definition for ‘hospital grade disinfectant’ already reflects use of these products in such a setting (and excludes podiatry practices). Use of existing terminology and definitions is of greater preference.

Ultimately a hospital and other consumers can choose whichever product they like regardless of how it is advertised. Therefore, labelled claims and recognised hospital grade products, which are the current markers of regulatory burden and product efficacy, would become meaningless. It’s possible that such labelled claims would be able to be used without regulated substantiation.

OPTION 4

Interpretation:

This approach is based on both the revised definition of *hospital grade disinfectant* and the labelled claims made (i.e. *specific* and *non-specific*, as currently defined in the Guidelines to TGO 54), effectively meaning that:

- *Hospital grade disinfectants* are regulated by TGA.
- Disinfectants with *specific claims* are regulated by TGA.
- All other disinfectants (excluding medical device disinfectants) are regulated by NICNAS.

Special Notes

- *This option is effectively a combination of options 1 and 2.*
- *This framework would most closely follow the initially released ‘summary of regulation for disinfectants and sterilants’ by the TGA in July 2005.* (See this document in Appendix C)

This combination also effectively combines the advantages and avoids the major disadvantages of each individual option:

Advantages

For Consumers: Maintains customer expectation and understanding that ‘hospital grade disinfectants’ are assessed according to efficacy.

For Consumers: All products claiming to have effectiveness against high level risks (e.g. viruses) will be assessed for efficacy. Hospitals will not be able to use a *commercial grade disinfectant* that has these specific claims without it having been assessed for efficacy.

For All: Easy identification of products that belong in each group.

For Industry: Reflects the current standard of assessment for products with specific claims. All competitors that want to make specific claims will be subject to the same controls regardless of the product application. The manufacturer would still be required to maintain records to the same level as is currently required for products with specific claims.

For All: Those products that would have fallen to NICNAS scope (under option 1 or 2) and caused excessive increase of financial and regulatory burden for both industry and the regulators will remain under the jurisdiction of the TGA, ensuring the products meet customer expectation and be assessed for efficacy.

Disadvantages

For Industry: A smaller number of products (than in options 1 or 2) would move to the jurisdiction of NICNAS.

Therefore, potential still remains for an increase in financial and regulatory burden placed on importers/manufacturers of household/commercial grade products with non-specific claims that have previously not required entry of all chemical entities on AICS. (This would also apply to antibacterial clothes preparations, sanitisers, etc) *See **Note 1** for further comments.

For Regulators: Increase (though less than in options 1 or 2) in the number of assessments for chemical entities on the AICS.

For All: Labelled ‘hospital grade products’ are not included, and therefore customer expectation that these products undergo efficacy testing is not met. *Note: The implementation of Part 1 of Recommendation 3 would solve this issue.*

Note: Refer to the table in Appendix B (and also on page 1) to observe that this option essentially changes the current regulations so that:

- All currently ‘exempt’ products (Household/commercial grade disinfectants, Antibacterial clothes preparations, sanitisers and sanitary fluids and powders) would become ‘excluded’ from TGA legislation and therefore come under the jurisdiction of NICNAS, and;
- All other disinfectants would remain under the scope of TGA legislation.

3. RECOMMENDATION 3

This recommendation is very confusing as its implementation and interaction with the other recommendations and options has not been explained.

The only way that this recommendation can be wholly and effectively implemented is only if it is used to build upon the implementation of Option 1 of Recommendation 1, which is indicated to be the Author's (Dr Simon Brooke-Taylor) preference (see page 30 of the Report).

We do not consider Option 1 to be the best option available, according to the reasoned assessment presented on the previous pages, and therefore do not support the implementation of the whole of Recommendation 3.

Alternatively, we have divided this recommendation into two parts:

Part 1: *All disinfectant products labelled "hospital grade" whether carrying specific biocidal claims or not, will be classified as therapeutic devices and be required to be listed on the ARTG.*

Part 2: *All commercial and household disinfectants, except products labelled as "hospital grade", whether carrying specific biocidal claims or not, antibacterial cleansing wipes; and sanitisers, cleaners and deodorisers, will be regulated by NICNAS.*

In contrast to the Report author's preference, it would be of greater advantage for only Part 1 of this recommendation is used to complement the selection of Options 1 or 4.

As a result, all disinfectants which are labelled as 'hospital grade', regardless of claims, place of use, or other characteristics, would be regulated by the TGA. All other disinfectants would be regulated as specified in the selected Option.

Such implementation would be supported as it would capture these products within the TGA framework and reflect customer expectation that products advertised for use in hospitals undergo efficacy evaluation.

It is predicted that this approach would be objected to by some manufacturer's that currently use such labelling without a requirement TGA assessment.

However, any such manufacturers do so as a marketing decision in order to take advantage of the assumption by consumers that such a product undergoes assessment of efficacy.

It is therefore only common sense that these products should in fact undergo such an assessment.

4. RECOMMENDATION 4

This recommendation includes the suggestion that:

‘...further consideration should be given to procedures to avoid unjustified regulatory burden being placed on manufacturers and to avoid duplication of assessment by TGA...’

As mentioned on page 3, greater regulatory burden will be placed on manufacturers with the implementation of any scheme that involves the movement of products from the jurisdiction of the TGA to NICNAS.

The level of burden will be greatly influenced by the way in which the new schemes are administrated.

One way in which NICNAS and the TGA can cooperatively reduce this impact is to compare, by CAS number, the formulation records currently held by the TGA (for Listed and Registered disinfectants) to chemical entities listed on the AICS (both public and confidential sections) and to transfer any necessary entities. This process would not require any input from the sponsors or manufacturers as this information will have been previously supplied to the TGA.

The Report recommends that such chemicals can be listed on the AICS using a facility to distinguish that they are only for use in disinfectants. It is inferred that such a listing would reduce the time and level of assessment involved, and so would be favourable to all.

This would avoid multiple sponsors or manufacturers making application to NICNAS for the same chemical entity.

It would also prevent any cases of unfair regulatory and financial burden placed on sponsors or manufacturers who are the first to apply and gain listing on the AICS for chemical entities which are common to other sponsors or manufacturer's products.

At present, only the first company to apply for inclusion on the AICS is charged assessment fees and required to provide information. These fees are very high (approximately \$15,000 for a Standard Assessment of a New Chemical Entity). Once the chemical is listed, other companies would be able to then introduce the same chemical without any financial or regulatory burden.

This type of issue does not occur in product based schemes as products between manufacturers vary and automatically require a new application. In product based schemes all applications of the same type are subjected to the same regulatory and financial requirements.

On the assumption that some sort of transitional period will be in place for any legislated changes, sponsors and manufacturers would be reluctant to be the first to lodge any new chemical entity applications. Sponsors and manufacturers would be likely to delay:

- a. In the hope that other sponsors or manufacturers will take on this regulatory and financial burden first; and
- b. In order to postpone the large out-lay of fees.

Consideration should at least be given to a reduction of the fees associated with new chemical entity assessment so that these effects can be minimised and sponsors and manufacturers are encouraged to actively participate in the transitional period.

It is also suggested that an exhaustive evaluation of hazardous components of disinfectants is generally not appropriate as these components are usually on a very small percentage in the final product, which in the case of NICNAS evaluation, is not currently taken into account. If the evaluation required for new chemical entities present only in disinfectants is reduced to a more appropriate level, it follows that a further fee reduction is also necessary and appropriate.

So, a comparison of the two databases (TGA formulations and NICNAS/AICS) as described, combined with a limited assessment by NICNAS/TGA of any chemicals found not to be already on the AICS, would be considered an effective way to reduce the additional financial and regulatory burden placed on manufacturers.

If individual applications by sponsors and manufacturers are still required, then a reduced assessment and fee reduction to encourage early participation in a transitional period would be necessary.

NOTE 1

As is mentioned in other sections of these comments, a significant increase in regulatory and financial burden would be apparent for manufacturers and sponsors with the implementation of any scheme which moves products from TGA to NICNAS jurisdiction.

This would occur due to the requirement of NICNAS/AICS assessment and registration of New Chemical Entities. Such a 'Standard Assessment' is currently listed as being approximately AU\$15,000 on the NICNAS fees and charges for 2007/2008.

A rough estimation, based on a company with current and pipeline chemical products (ranging in application from Hospital Grade to Household/Commercial Grade disinfectants) to a total of 50, with an estimated 15 new chemical entities to register, would incur additional regulatory fees of AU\$225,000^a.

This is of course a rough estimate of the impact that implementation of some options can incur, but clearly highlights the need for careful consideration of the options and method of implementation.

The benefits to all parties (customers, regulators and industry) in comparison to the regulatory burden must be seriously considered. It is suggested that such a high cost and burden with little additional benefit to the current regulatory environment is excessive.

It is evident that movement of the smallest amount of products from TGA to NICNAS scope, if any at all, is preferable to industry, regulators and customers as such a financial impact will have follow on effects to all sectors.

^a Based on the following estimation from brief assessment:

- Most products contain 15-20 chemical entities, of which, in one out of five products, 2-3 entities are not currently on the AICS.
- Therefore, taking an estimate that for every five products, 3 chemical entities need to be registered, a pipeline of 50 products will require 30 new chemical entity assessments by NICNAS.
- Taking a conservative approach that of these 30 chemicals, approximately half are repeated somewhere in each of the formulations, we can reduce this number to 15 new chemical entity assessments by NICNAS.

NOTE 2

One issue that is of great significance, but was not addressed in the report, is the level of assessment that would be required for disinfectant products that remain under TGA jurisdiction.

This is a very important consideration in the implementation of such schemes as the regulatory burden on Industry and Regulators can be vastly impacted by such a decision.

This issue was somewhat addressed at the information session, where the TGA indicated that all disinfectants remaining under the TGA scope would be assessed as being Listable Other Therapeutic Goods and that the requirement for Registration would be removed.

This is also reflected in the *'Summary of regulation for disinfectants and sterilants'* released by the TGA in July 2005 (Appendix C).

Such a change would be of great advantage to both Industry and Regulators as the lengthy time frames and high costs associated with currently required Registrations would no longer restrict the introduction of new technology to the marketplace.

The TGA also indicated that at present there are only 10 such registered disinfectants, while there are approximately 150 listed disinfectants.

This clearly suggests that such a restriction currently exists. As a result it is quite possible that the Australian disinfectant marketplace, for those products with specific claims, is very disadvantaged in the technology available for combating biological contamination and spread of disease.

It is suggested that the assessment involved in the Registration of a disinfectant is outdated and no longer required, and that, by making all of these type of disinfectants Listable Other Therapeutic Goods, that the level of regulation remains equivalent.

In such a change all products would still be required to meet the relevant sections of TGO 54, but the restrictions of a lengthy assessment would be removed. Compliance could be established, if required, by random audits as are routinely conducted by the TGA for medical devices.

APPENDIX B

Comparing the recommendations in 'A new Regulatory Framework for Disinfectants' by Dr. Simon Brooke-Taylor

Type of Product	Current requirements	Report Recommendations - Requirements if implemented & Basis of legislation			
		1, 2(option1) & 3(Part 1)	2(option2)	2(option3)	1, 2(option4) & 3(Part 1) Device Technologies supported options (Close to TGA July 2005 proposed changes)
		1. New definition of 'Hospital Grade Disinfectant'	Recommendations 1 and 3 become redundant if option 2 is implemented	Recommendations 1 and 3 become redundant if option 3 is implemented	1. New definition of 'Hospital Grade Disinfectant'
		2(option1). Based on new definition for Hospital Grade Disinfectants	2(Option2). Based on labelled specific or non-specific claims.	2(option3). Based on product use in a 'clinical setting'	2(Option 4). Based on new definition for 'Hospital Grade Disinfectant' and labelled specific or non-specific claims
		3(Part 1) Labelled 'hospital grade' disinfectant products to be regulated by the TGA	-	-	3(Part 1) Labelled 'hospital grade' disinfectant products to be regulated by the TGA
Sterilant & Instrument Grade Disinfectants	TGA - Class IIb medical device	no change - outside scope	no change - outside scope	no change - outside scope	no change - outside scope
Detergents & Medical Device Cleaners	TGA - Class I medical device	no change - outside scope	no change - outside scope	no change - outside scope	no change - outside scope
Hospital Grade Disinfectant - specific claims	TGA - OTG - Registrable	TGA - OTG - Listable	TGA - OTG - Listable	Disinfectants used in 'clinical setting' regulated by TGA. Others regulated by NICNAS + codes of conduct.	TGA - OTG - Listable
Hospital Grade Disinfectant - non-specific claims	TGA - OTG - Listable	TGA - OTG - Listable	NICNAS + codes of conduct		TGA - OTG - Listable
Labelled 'Hospital Grade' Products	Dependant on labelled claims and use	TGA - OTG - Listable	Dependant on labelled claims and use		TGA - OTG - Listable
Household/Commercial Grade Disinfectant - specific claims	TGA - OTG - Registrable	NICNAS + codes of conduct	TGA - OTG - Listable		TGA - OTG - Listable
Household/Commercial Grade Disinfectant - non-specific claims	TGA - OTG - Exempt from ARTG	NICNAS + codes of conduct	NICNAS + codes of conduct		NICNAS + codes of conduct
Antibacterial clothes preparation	TGA - OTG - Exempt from ARTG	NICNAS + codes of conduct	NICNAS + codes of conduct		NICNAS + codes of conduct
Sanitisers	TGA - OTG - Exempt from ARTG	NICNAS + codes of conduct	NICNAS + codes of conduct		NICNAS + codes of conduct
Sanitary fluids & powders	TGA - OTG - Exempt from ARTG	NICNAS + codes of conduct	NICNAS + codes of conduct		NICNAS + codes of conduct
	NOTE: All currently need to comply with TGO 54	NOTE: Only TGA regulated products need to comply with TGO 54	NOTE: Only TGA regulated products need to comply with TGO 54	NOTE: Only TGA regulated products need to comply with TGO 54	NOTE: Only TGA regulated products need to comply with TGO 54

APPENDIX C

July 2005 TGA Proposed Changes



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Summary of regulation of disinfectants and sterilants

Product Category		ARTG Status	Requirements	GMP Licensing
A	Sterilant	<i>Registrable</i> (Schedule 3 Part 2)	TGOs54, 54A & 54B +AUST R	Manufacturer Licensing Required
B	Instrument grade disinfectants - high level - intermediate level - low level	[Now Included Medical Devices Class IIb]	[New Medical Device Standard Order based on TGO 54 drafted]	Conformity Assessment Certification required
C	Hospital grade disinfectants - with specific claims	<i>Registrable</i> (Schedule 3 Part 2)	TGOs54, 54A & 54B +AUST R	Not Required
D	Household/commercial grade disinfectants - with specific claims	[Proposed to be Listable]	[Updated TGO 54 & Guidelines]	
E	Hospital grade disinfectants - without specific claims	<i>Listable</i>	TGOs54, 54A & 54B + AUST L [Updated TGO 54 & Guidelines]	Not Required
F	Household /commercial grade disinfectants - without specific claims - new chemical entity	<i>Exempt</i> [Proposed to be Listable]	TGOs54, 54A & 54B [Updated TGO 54 & Guidelines]	Not Required
G	Household /commercial grade disinfectants - without specific claims	<i>Exempt</i>	TGOs54, 54A & 54B [Updated TGO 54 & Guidelines]	Not Required
H	Sanitisers *	<i>Exempt</i>	TGOs54 & 54A & 54B	Not Required
I	Sanitary fluid *	[Proposed to be Excluded]	[Not Required if Excluded]	
J	Antibacterial clothes preparation *			

The term 'specific claim' is currently defined in the TGA document 'Guidelines for the Evaluation of Sterilants and Disinfectants' as one which covers virucidal, sporicidal, tuberculocidal, fungicidal or other biocidal activity.

A 'non-specific claim' is a claim which includes general antibacterial action or activity against vegetative bacteria (excluding mycobacteria) covered by the battery of test organisms included in the specified test, or bacteria of the same genus.

* Proposed to be excluded from TGA's controls under Section 7 of the Therapeutic Goods (Excluded Goods) Order.

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APPENDIX D

Current Legislation Definitions

From TGO 54:

Hospital Grade Disinfectant

"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;

Household/Commercial Grade Disinfectant

"household/commercial grade disinfectant" means a disinfectant that is suitable for general purpose disinfection of building or fitting surfaces, and for other purposes, in premises or involving procedures other than those specified for a hospital grade disinfectant, but is not:

- (a) an antibacterial clothes preparation; or
- (b) a sanitary fluid; or
- (c) a sanitary powder; or
- (d) a sanitiser;

From TGO 54 Guidelines:

Specific Claims

"specific claim", is one which covers virucidal, sporicidal, tuberculocidal, fungicidal or other biocidal activity. Except where claims of activity against fungi (yeast and mould) for excluded products are concerned, such claims lift a product into the registrable category of goods.

Non-Specific Claims

"non-specific claim", is a claim which includes general antibacterial action or activity against bacteria covered by the battery of test organisms included in the specified test, or bacteria of the same family. Claims for bacteria other than these are allowable and do not cause the product to become registrable, but the specific organism against which activity is claimed must be included as an extra organism in the test battery eg. *E. coli O157*, *Salmonella spp*, *Streptococcus spp*, etc.

From the Act:

Therapeutic Goods

therapeutic goods means goods:

(a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:

(i) for therapeutic use; or

(ii) for use as an ingredient or component in the manufacture of therapeutic goods; or

(iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or

(b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii);

and includes medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include:

(c) goods declared not to be therapeutic goods under an order in force under section 7; or

(d) goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or

(e) goods (other than goods declared to be therapeutic goods under an order in force under section 7) for which there is a prescribed standard in the Australia New Zealand Food Standards Code as defined in subsection 3(1) of the *Australia New Zealand Food Authority Act 1991*; or

(f) goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.

Therapeutic Use

therapeutic use means use in or in connection with:

(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or

(b) influencing, inhibiting or modifying a physiological process in persons or animals; or

(c) testing the susceptibility of persons or animals to a disease or ailment; or

(d) influencing, controlling or preventing conception in persons; or

(e) testing for pregnancy in persons; or

(f) the replacement or modification of parts of the anatomy in persons or animals.

Therapeutic Device

therapeutic device means therapeutic goods consisting of an instrument, apparatus, appliance, material or other article (whether for use alone or in combination), together with any accessories or software required for its proper functioning, which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means though it may be assisted in its function by such means, but the expression does not include therapeutic goods declared by the Secretary, by order published in the *Gazette*, not to be therapeutic devices.

Medical Device

A **medical device** is:

(a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

(iii) investigation, replacement or modification of the anatomy or of a physiological process;

(iv) control of conception;

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or

(b) an accessory to such an instrument, apparatus, appliance, material or other article.

Note: Declarations under subsection (3) exclude articles from the scope of this definition. Declarations under section 7 can also have this effect: see subsection 7(4).