



AEA client newsletter - special edition

In January the TGA released consultation drafts of four new Therapeutic Goods Orders that will affect medicines in many different ways. As a service to our clients and newsletter subscribers we have summarised the major differences to the current requirements. While time is getting short, there is still time to submit comments through your industry association or directly to the TGA.

The final Orders will not come into effect until July 2009 or July 2010, however some of the changes (e.g. label statements) have long lead times so we recommend checking products carefully against each Order to determine the changes that could be required. If you require assistance we have processes in place for quick and efficient review against the new requirements .

TGO79 - General requirements for the labelling of medicines

Major changes include the following: The quantity of actives for registered medicines must be stated in 2mm font size; there are new provisions for 'very small containers' (<=2mL); excipient declarations for prescription medicines must now be on the label or pack insert; additional declarations are required for crustaceans, egg, fish, milk, potassium salts, sesame, soya bean and tree nuts; there are some changes to definitions and new arrangements for 'starter packs' and 'medicine kits'.

Click [here](#) for a more detailed summary

TGO78 - General requirements for tablets and capsules

There are now separate requirements for listed and registered medicines; the content of active for listed medicines generally is now 90 - 120%; the existing wider limits for content of certain actives (e.g. minerals, vitamins) have changed; new registered medicines must comply with the BP 'Uniformity of dosage units' monograph and compliance with a suitable dissolution test is now a requirement for all registered medicines if the BP or USP requires a dissolution test for that active (currently only required for nominated actives).

Click [here](#) for a more detailed summary

TGO80 - Child resistant packaging for medicines

The draft TGO80 will apply to a greater number of products and product categories than TGO65. Compliance with one of 5 nominated standards will be required. In addition, products tested against previous versions of a standard may need to be tested against the current version. Additional product-specific testing will be required to ensure fitness of purpose and retention of child-resistant properties for the duration of the shelf life.

Click [here](#) for a more detailed summary

TGO77 - Microbiological standards for medicines

This Order is due to come into effect on 1 July 2009 (the others are on 1 July 2010). It replaces existing provisions in various TGA guidelines. Multidose medicines must comply with the BP 'Efficacy of antimicrobial preservation' monograph, except for oral antacid medicines which are expected to meet the less rigorous requirements of the USP. Tests and limits for microbial content of non-sterile medicines are to be aligned with the BP - the Australia-specific requirements in the current guidelines will no longer apply.

Click [here](#) for a more detailed summary

Contact us

If you require more detailed information or specific guidance on how the proposed Orders will affect particular products.

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