

TGA AUSTRALIA

RE: CF030103
16 January 2019

Comment on
"Remaking Therapeutic Goods Order No. 78 –
Standard for Tablets and Capsules
and reintroducing pills into the remade Order"

Chemistry First Pty Ltd, a food chemistry and laboratory consulting incorporated in Australia, would like to comment on the TGO order as following -

The provision of the draft

“(4) If:

(a) the tablet or capsule contains an active ingredient that comprises two or more components that are each quantified on the label of the medicine; and
(b) the proportions of these components vary independently of each other;
then the estimated average content of each component in a pooled sample of not fewer than 20 tablets or capsules must be not less than 90.0 per cent of the stated content of the active ingredient.”

constitutes permanent manufacture of tablets and capsules with 10% less AI.

This provision should be amended to

- *Increase requirement to 95% and include CC charts to use CC chart rules;*
- *Criteria need to be developed for frequency of tests and tolerances;*
- *Include measurements of homogeneity, at least periodically, eg yearly or 6-monthly and every time the process or AI is changed.*

Thank you,
Kind regards.

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Consultant