



S38A Guidelines Project Officer
Office of Manufacturing Quality
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Monday 14 December 2009

Dear Sir/Madam

CHC Comment –Proposed S38A Guidelines for Australian Manufacturing Licences Covering Multiple Manufacturing Sites

Thank you for the opportunity for the complementary healthcare industry to provide comment on the S38A Guidelines for Australian Manufacturers which allows for the issuing of a single manufacturing licence that authorises the manufacture of therapeutic goods at more than one manufacturing site or location, dated November 2009.

Specific Comments

The Complementary Healthcare Council (CHC) supports the Therapeutic Goods Administration (TGA) guidelines relating to the issuing of single manufacturing licences and believes that they will provide clarity for complementary medicine manufacturers, however the following comments have been provided for consideration:

- Section 9, *“Once an on-site audit has commenced, the total travel time between premises must not exceed 30 minutes”*. The CHC considers that the stated travel time of 30 minutes between sites may not be appropriate. The distance travelled in 30 minutes in the CBD is substantially different compared to travel times in rural areas. The CHC proposes using kilometres to define distance as this will allow a level playing field across all manufacturers, no matter their location.
- Secondly, the CHC points out that the ‘NOTE’ at the end of the proposed guidelines states *“In either of 7 or 8 above, where additional manufacturing steps are also performed at the additional fixed storage site, the TGA will consider a request to authorise these additional steps, in the licence, if the other criteria are met.”* This note should be amended to also include Sections 5 and 6 (in addition to 7 and 8). At present, the guidelines only capture the manufacturing of *‘blood, blood components, plasma, haematopoietic progenitor cells or human tissue’*; with the suggested changes, manufacture of medicines and other therapeutic goods (Sections 5 and 6) would also be able to negotiate with the TGA in relation to licensing.

If you would like to discuss any matters within this submission further please do not hesitate in contacting me.

Yours sincerely

Kristy Tomas
Scientific & Technical Manager