18 December 2020

Manufacturing Quality Branch
TGA
gmp@tga.gov.au

Re: Consultation on TGA Guidelines for compounded medicines and good manufacturing practice (GMP) - Guide to the interpretation of the PIC/S guide to GMP for compounded medicinal products

Medicinal Cannabis Industry Australia (MCIA) welcomes the opportunity to make comment on TGA Guidelines regarding compounded medicines and good manufacturing practice (GMP), namely the document "*Guide to the interpretation of the PIC/S guide to GMP for compounded medicinal products".*

About Medicinal Cannabis Industry Australia (MCIA)

MCIA is the peak industry organisation for Australia's licensed medicinal cannabis industry. This encompasses all activities of medicinal cannabis licence holders across research, cultivation and manufacturing and interaction with patients, the medical profession and communities.

MCIA's focus is on building an industry that enhances wellbeing through facilitating access to quality Australian medicinal cannabis products for Australian and global patients.

Medicinal cannabis has an important role to play in improving health outcomes. MCIA supports a holistic healthcare approach built around patients and their regular medical practitioner determining if medicinal cannabis is an appropriate medicine for their current medical condition. MCIA believes that patients should have easy and affordable access to a quality controlled, true to label, compliant product that is demonstrating the potential to positively contribute to a broad range of conditions.

Compounding and medicinal cannabis

MCIA recognises the need for single use compounding (i.e. compounding medicine for one patient) in Australia and agrees with the principles set out in the consultation guide. However, MCIA is concerned about reports from some of its members that some compounding pharmacies are producing batches of products when they should only be compounding one supply of medicine per prescription. While noting that pharmacists are allowed to compound in anticipation of an order where a patient has a defined course of treatment, it appears that some pharmacies are producing volumes above what one patient would require.

MCIA is concerned that compounding pharmacists may be producing large batches of medicinal cannabis products and selling them at a later date. This is of concern given the potential adverse impacts for patients if there are issue with stability or other aspects of medicinal cannabis products. While we are unclear of the standard to which products need to be produced, noting that it is not Good Manufacturing Practice (GMP), if the compounding pharmacy had to sign off as an Australian sponsor as per TGO93, this would potentially reduce risks.

Additional to the concern that medicinal cannabis products may be being produced in large batches, is whether products are being tested for potency in line with their rotational testing requirements, further adding to safety concerns. The allocation of expiry dates for compounded goods and requirement to provide stability testing in equivalence to TGO93 could assist to reduce risks to patient safety.

MCIA does not have any specific issues with the guidance document itself, but believes there is scope to include some thought regarding enforcement and more comprehensive auditing and accountability. The main concerns for MCIA focus on public safety and are listed below.

- Line 263 of the guidance document states that:

  "You must notify the Secretary every quarter (within 15 days from the end of that quarter) of the goods manufactured for that quarter and who they were supplied to, if you manufacture and supply extemporaneously compounded medicines in accordance with Schedule 5A, item 5 of the *Therapeutic Goods Regulations 1990*."

  MCIA would like to know how this might be enforced and whether there is any follow up action for pharmacies that appear to be producing excessive amounts of single use medicine.

  Additionally, MCIA would ask whether such facilities are audited to determine if they are reporting accurately.

- At line 295 it states:

  "This exemption does not permit manufacture in advance of an order, nor does it permit bulk manufacture of multiple units for later dispensing"

  MCIA would ask again how this would be detected and what penalties the Department of Health may enforce for repeat offenders

- MCIA is also concerned regarding the content, and quality, of compounded medicinal cannabis. It is necessary to audit these pharmacies and perform some testing on the compounded product to determine whether the contents in the medicine match the label – as is strictly required for the entire medicinal cannabis industry. This testing would also look at excipients and any other additives, and the methods used in their production, packaging and storage prior to supply.

Ultimately, the main concern is to ensure public safety through the production of effective, high quality medicine. While every medicine can be checked before being dispensed, the difficulty is how to confirm that it is stable, true to label and has an expiration date applied if it is compounded in large batches. There is a need to ensure that compounding pharmacists are only compounding medicine as necessary on a per patient basis and not stockpiling because it is commercially beneficial to do so. This could significantly compromise public safety and adversely affect our emerging sector.

We appreciate your consideration of the above comments and would be happy to supply additional information if required.

Regards

Rosemary Richards
Executive Manager