Supporting Australia with Pharmaceuticals, Medical Equipment and Consumables

anspec
Health Products Supply Services

TGA Changes and Bud compliance with TGO-100/ICH regulations (under GMP)

Dear Doctor, Pharmacist, clinician, client,

On behalf of Anspec I want to clarify for you the impact of the recent TGA announcements as they apply to the services Anspec provides and to assure you that Anspec services are unchanged by the announcements as Anspec has always remained aware of, and compliant with, all regulations.

The products supplied by clients through Anspec also remain unaffected as their manufacture or import has always been required to meet the relevant standards including TGO-100 or ICH (International Council on Harmonisation of Technical Requirements of Pharmaceuticals for Human Use) under GMP which is the same wording.

As many of you know I am also responsible for an Australian GMP manufacturer of Cannabis and that manufacturer welcomes and embraces this emphasis on quality of Australian product by the TGA along with our clients and our distributor.

Unfortunately, the process of “declaring” compliance with TGO-93 to TGA was, by some companies, mistaken to mean that they could rely in some way upon TGA as a measure of quality for unregistered cannabis medicines. This was never true.

Because Anspec has been distributing, importing, and exporting both registered and unregistered medicines for over 30 years Anspec is well aware of this.

Also unfortunately, a number of companies “declared” compliance when the products were not compliant, and this has become an even bigger problem as patients start to access cannabis in dried bud form. Any Cannabis that is imported for inhalation must meet the standard of TGO-100. This is simply the International Pharmacopeia requirements or ICH Guidelines which apply in Australia for

protection of consumers of medicines. This standard ensures that the product has a very stringent and low microbial count (far less fungus, mould, etc.,) so that it can safely be inhaled.

Also, for Australian manufactured product, the equivalent is “release for supply under GMP” but some of the Australian manufacturers of dried bud seem to have been doing this without reference to the ICH medicines regulations for inhaled product.

Basically, these non-compliant products, whether imported or Australian made, only comply to the “Oral Dosing” standards which requires the medication to be made into a tea with boiling water to kill the microbes (fungi, moulds, etc.,) that are present.

At Anspec, we insist on reviewing the Certificate of Compliance (CoA) of the products that we distribute to ensure that those CoA’s comply with TGO-93 and, if for inhalation, TGO-100.

As insured doctors and pharmacists it is very important that you only prescribe or dispense compliant product.

Importantly, Doctors have full responsibility for any unregistered medicine they prescribe. This is where all compliance responsibility starts. Pharmacists need to support the doctors in ensuring that compliance and raising any concerns they may have around compliance of any given product under TGO-93 or TGO-100 for imported medicine or the same standards under ICH for Australian manufactured. Doctors in the employ of a practice should be careful to realise that responsibility is with the doctor and not the practice nor clinic.

TGA has made quality compliance and quality patient care possible by allowing SAS-B or -AP status to proceed without a brand specified so that Doctors, Pharmacists, other advising clinicians and even patients can check and ensure that the medicine they receive meets the standards.

TGA have also announced that they will increase compliance testing which is a great step-up in making Australia a global leader in opening access to Cannabis as a health product.

Anspec has previously provided independent testing services for clients wishing to ensure the quality of their own product.

Some manufacturers have taken the expedient step of starting internal testing labs where they test their own compliance and verify internally. External validation and independent testing remains important to improve integrity.

Some other problems have also arisen in the industry where “clinics” are offering to move large numbers of their patients to a particular brand of medicine in exchange for more favourable commercial terms. This practice was long ago stamped out of the pharmaceutical and medical device industries. This practice also “killed” the Canadian Medicinal market.

Unfortunately, following recent announcements, it has been said that some large pharmacies specifically focussed on cannabis are now hoping to do the same thing to increase profit margins. I would point to recently publicised actions on enforcement by Securities and Commercial watchdogs on cartel type behaviour, price fixing, or other frowned-upon practices in the pharma industry as a cautionary note.

In conclusion, many companies have worked hard and competed fairly to give access to medicinal cannabis to Australian’s whom have need or whom can benefit. We have been careful not to give any excuse to those whom still do not understand the benefits of medicinal cannabis and to keep the industry safe.

Properly implemented, these changes by the TGA help us to continue to grow Australia as a global leading light to sustainable access to the benefits of cannabis for health.

Peter Comerford

Chief Executive Officer

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