Accessing Medicinal Cannabis Products
Follow-up Commentary on *Lateline* story aired on 23 August 2017

25 August 2017

Last night, Lateline aired a story providing evidence of a "policy position" taken by the Office of Drug Control to block the importation of medicinal cannabis products for terminally ill patients under Category A of the Special Access Scheme (Category A import). This "policy" is being applied notwithstanding the Senate's disallowance in June of amendments to the *Therapeutic Goods Regulations 1990* (TG Regulations) which would have blocked all access to medicinal cannabis imports under Category A of the Special Access Scheme.

The Lateline story can be viewed at http://www.abc.net.au/lateline/content/2016/s4723199.htm.

For the benefit of industry stakeholders, medical practitioners, patients and other interested parties, we set out below our understanding of the current legal framework as it pertains to Category A imports.

The relevant legislation concerning the importation of drugs is the *Customs (Prohibited Imports) Regulations 1956* (Cth) (**CPI Regulations**), which provide that the importation of a drug is generally prohibited unless the importer holds both an import licence and permission (*i.e* a permit).

The CPI Regulations further provide that if an application is made, in the required form, for a permission to import a drug, the Secretary **shall** grant the permission (subject to the applicant furnishing all of the information requested by the Secretary and holding a licence authorising the sale or supply of the drug in the State or Territory in which the applicant's business premises are situated).

Accordingly, under the CPI Regulations, the Secretary does not appear to have any discretion to refuse to grant an import permit if the applicant meets the requirements set out above. Subject to those requirements being met, there can be no proper basis for the Secretary to refuse to grant a permit for a Category A import.

We note, however, that subregulation 5(13) of the CPI Regulations provides that an import permit *"may specify conditions or requirements, including conditions or requirements with respect to the possession, safe custody, transportation, use or disposal of the drug, to be complied with by the holder of the permission and may, in respect of any such condition or requirement, specify the time, being a time before or after the importation of the drug, at which the condition or requirement is to be complied with by the holder of the permission."* This appears to be the basis upon which the ODC has, up until the disallowance at least, imposed conditions upon import permits relating to medicinal cannabis products limiting supply to patients under Category B of the Special Access Scheme or the Authorised Prescriber Scheme, or for use in clinical trials.

Having regard to the above, technically speaking, the letter issued by the ODC to importers is correct in stating that if a condition on an importer's permit does not allow supply for the purpose of Category A patients, any such supply would be a breach of both the import licence and the permit.

Disturbingly, however, the ODC appears to be indicating that all **future** import permits will continue to be subject to the above condition, stating: *"[i]n line with Australian Government **policy**, condition 1 will be **maintained** on all bulk imports of unregistered medicinal products"* (emphasis added). It

has also stated that companies "*will be advised if there are any changes to Government policy on this matter*".

This is a roundabout way of the ODC stating that, notwithstanding the Senate's decision in June to allow access to medicinal cannabis products for Category A patients, it will continue to block those patients' access by a different means – namely, by placing a condition on any import permit that imported medicinal cannabis be supplied only under the Category B, Authorised Prescriber or Clinical Trial schemes.

This is extraordinary for a number of reasons:

1. A company that holds an import licence is entitled to submit, in the correct form, an import permit application for the importation of drugs intended for supply to Category A patients, and the Secretary is ordinarily required to grant such a permit.
2. The supply of imported medicinal cannabis products to patients under Category A of the Special Access Scheme is lawful, following the Senate's disallowance in June. Further, Item 1(d) of Schedule 5A to the TG Regulations expressly provides for therapeutic goods to be imported into Australia and **held under the direct control of the sponsor until the goods are dispensed as a medicine prescribed for a Category A patient.** This is in keeping with the intention of the Category A scheme as a whole – to provide terminally ill patients with immediate access to medicines prescribed by their doctors.
3. Although subregulation 5(13) of the CPI Regulations allows the Secretary to impose conditions on an import permit, it would seem directly contrary to the intention and operation of the *Therapeutic Goods Act 1989* (Cth) and TG Regulations for the Secretary to impose conditions which would effectively block access to medicinal cannabis for Category A patients.
4. Any "policy" introduced in an effort to override the clear intention of the legislative scheme would likely be held invalid by a Court.

It remains to be seen whether the ODC will follow through on its letter by imposing conditions on future import permits to block Category A imports, or whether the letter is just an attempt to deter companies from submitting import permit applications for Category A purposes. It seems to us, however, that any such action would be legally tenuous – if the government had confidence in its use of sub-regulation 5(13) to block Category A imports, then why did it introduce the now disallowed amendments to the TG Regulations in the first place? On any view, it is a cause for deep concern that the Executive apparently feels sufficiently empowered to thumb its nose at the Legislature.

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