Access to cannabis for therapeutic use

Summary of policy

Introduce legislation to make medicinal cannabis available for people with terminal illnesses or in chronic pain.

Current state

People with a terminal illness/chronic pain can currently access cannabis products, via a medical practitioner. However, access to suitable products is currently limited and expensive.

Cannabis products can vary significantly in chemical compositions and their actions on people. This variation may be due to the plant variety, cultivation (e.g. hydroponics, pesticides) processing, and the individual.

Cannabis products currently prescribed in New Zealand are made to a standard, which will indicate their chemical composition and the manufacturing standards under which they were produced.

Where a medical practitioner wishes to prescribe a cannabis product, they must apply for approval from the Ministry of Health (except in the case Sativex which is an approved Medicine).

Issues

Increasing access to cannabis-based products for this population group needs to consider:

Timely access to appropriate cannabis-based products

Current approvals can be provided within a number of days but they depend on good information about the product and the active involvement of medical practitioners. Even when approval is granted, access can be slow as products usually need to be sourced from overseas. Importation can also be complex depending on the legal frameworks that exist in other countries.

Patient safety and outcomes

There is a lack of high quality clinical evidence to support the efficacy of cannabis for specific conditions and many medical practitioners are reluctant to raise expectations and encourage use, particularly if the product has an unknown composition. Very few products meet the usual standards for medicines sold in New Zealand. There is also a risk of harm if products contain contaminants.

Reducing cost of appropriate product

Emerging therapeutic products are very expensive and these costs are currently met by individuals. Products that meet a lower standard may be less expensive. Pharmac currently hold responsibility for decisions about the funding of pharmaceuticals in New Zealand. Governments in other jurisdictions have financially supported domestic cultivation in order to increase supply.

Next steps

Depending on the Government's policy intent, there are two options:

- Government takes over Julie-Anne Genter's Private Member's Bill. If the Government proceeded with the Private Members Bill, we can provide advice on potential modifications that may be required to improve the Bill.
- A new Government Bill is developed. A cabinet paper will be developed to agree policy.

We can also provide further advice on non-legislative changes that can be made immediately to enhance access. For example the Ministry of Health can under existing regulations issue licences for the cultivation of cannabis for therapeutic cannabis products, reduce approvals processes when cannabis products is prescribed, and/or allow provisional approval for emerging cannabis products.

IN CONFIDENCE - WORKING DRAFT

Questions to consider to increasing access

What is meant by medicinal cannabis?

Medicinal cannabis can refer to:

- Approved therapeutic products. The current approach has focused on applying the approach used for other medicines. Under
 this approach, medicines may be approved by Medsafe or may be prescribed by doctors as 'unapproved products'. These
 products meet a high standard in terms of manufacture and consistency of content.
- Other manufactured cannabis products that meet basic standards. There are international examples of other products that meet very basic standards, for example these products may not have clinical trial data but may have a known composition and have been tested for contaminants. These products could be made more easily available on prescription under current law by changing regulation and approvals processes.
- Any cannabis. Cannabis currently grown or sold illegally may not be made to any standard or have known composition but could be more cheaply and freely available. Access to cannabis generally will require legislative change.

Who will have enhanced access?

The manifesto commitment refers to making medicinal cannabis available for people with terminal illness or in chronic pain. The new legislation will need to set out a process for determining who can access products.

- The current medical model restricts access to a patient where a medical practitioner makes a clinical judgement that the person would benefit. or
- A medical practitioner could provide medical certification for a qualifying condition, but not have a role in recommending or prescribing a specific cannabis product.

One factor to consider is how comfortable the medical profession will be in playing a role where a product of unknown efficacy or chemical composition will be made accessible to their patient. If doctors are unwilling to recommend products, then access may remain limited.

How will cannabis products be supplied?

A key issue internationally, has been the availability of suitable products that meet usual standards. Without a legitimate supply route, legislation to support access may still leave individuals having to act outside the law to buy products. There are a number of choice regarding enhancing supply including:

- Continue to reduce barriers to importing therapeutic cannabis products and domestic cultivation
- · Government can take an active role in supporting the cultivation and manufacture of products
- Enable individuals to grow their own supply, and/or exchange within cooperative arrangements.

Australia

Australia has developed a regulatory framework for domestic cultivation of cannabis-based products made with some quality requirements. The objective is to enable access to affordable product for patients with qualifying conditions. The framework regulates the commercial cultivation and manufacture of cannabis and includes fit and proper person requirements + security and compliance inspections. Licenses have been issued for cultivation and manufacture but the framework is yet to deliver product to patients.

The Ministry understands that the Australian system is deemed to be UN compliant and that expert input on the type of products produced and patient eligibility criteria has been obtained from clinicians, ethicists, consumers and others.