Prescribing Medicinal Cannabis in Australia for Cancer Patients : A new era in medicine with all it’s complexities

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Introduction:

Australia has recently introduced the prescribing of Medicinal Cannabis for symptom management for selected patients. Initially indications were limited to:

- Cancer related refractory symptoms (CINV, Nausea, Anorexia, Pain)
- Chronic refractory pain
- Multiple Sclerosis
- Childhood refractory epilepsy.

Within the first year of introduction the Australian model is continually developing and changing. The rapid development of the field of medicinal cannabis in Australia and worldwide has resulted in a more flexible and timely approval process, increased investment in quality research and development of education programs for medical practitioners.

The Australian government’s intent : (1)

- Providing **patient access to Australian-grown** and manufactured medicinal cannabis outside the standard registered medicines route
- **Providing of Quality imported medicinal grade products** for prescription for patients via the Special Access Scheme (SAS)
- **Provision of a quality medicine** through doctors prescription
- **Encourage clinical trials** for potential future TGA registration
- The Health Products Regulation Group has **oversight Cultivation and manufacture** (Office of Drug Control)
- Product GMP, product scheduling and patient access through the **Therapeutic Goods Administration (TGA)**

Current Research and Clinical Trials in NSW, Australia (2)

Clinical Trials (Government Sponsored)	Pharma Sponsored Trials	Other Cannabis Research
Chemotherapy Induced Nausea and Vomiting	Cancer related pain	Epilepsy
Anorexia in Advanced cancer	Cannabis for recurrent GBM*	Motor neuron disease
Childhood Epilepsy	More....	Cancer and cancer related symptoms
Cannabinoids in Advanced Cancer, a Real life Evaluation *		Mental Health
		Entourage effect
		Drug addiction and behaviour
* J.Lacey CI		More....

Product availability as per May 2018

In March 2017: 3 companies supplying cannabis for trials and prescribers in Australia.
Currently 18 registered companies supplying medicinal grade cannabis in Australia: including local suppliers. (3)

References:

1. Adj Prof. John Skeritt, Deputy Secretary, Commonwealth Department of health, Australia. Medicinal Cannabis Education Course Book (MCE) May 2018.
2. NSW Health Centre for medicinal Cannabis research and innovation. <https://www.medicinalcannabis.nsw.gov.au>
3. The Office of Drug Control: Australian Government department of health <https://www.odc.gov.au>

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Criteria to Prescribe Medicinal Cannabis in Australia:

Depends upon the patients, product and prescriber

Authorised Prescribers or those applying via SAS scheme must:

- Have training and expertise appropriate for the condition and the proposed use of the product, and
- Be able to best determine the needs of the patient and to monitor the outcome of therapy

Provide: Patient and clinical justification

- Patient information, diagnosis and indication treated
- The seriousness of the condition
- Details of past treatment
- Expected benefits from the use of the product (1)

Applications for Medicinal Cannabis using Special Access

Scheme by medical practitioners since start of program

(March 2017-April2018) n=680 (1)

Cannabis in Supportive Cancer Care in Australia:

Barriers

- Persisting angst of clinicians to prescribe
- Uncertainty regarding products available & their efficacy and benefit
- Education required: First program for general practitioners (government and College endorsed “MCE”) May 2018, next September 2018. No formal programs for specialists in Palliative care or cancer care.
- Slow referral to CINV and Anorexia and cancer studies
- Access and approval was very slow for first 12 months limiting prescribing for patients with advanced cancer.
- Consumer literacy and misinformation by black market suppliers.

Facilitators

- Development of Guidance documents the by TGA and expert consultation process
- Improved access time (2 days compared with 4-6 weeks in most States since March 2018)
- Education and experience
- Improved product availability
- Consumer pressure and increased industry presence
- Opioid “epidemic” and improved cancer prognosis
- Champions involved in Clinical trials, educating and prescribing.