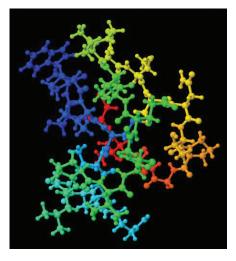
# S Market Market

## New Bio-Drugs a Step Closer



What if in the future, forests could be a veritable cornucopia of medicines, where instead of blister packs or safety sealed bottles, you picked leaves from a plant as you wandered past and then brewed them into a fresh tea as treatment for your disease? Whilst this vision is never going to be the main way we consume medicines, it may prove to be reality for a few, at least if research by two Australian professors reaches maturation. Professor David Craik, Institute of Molecular Biology, University of Queensland and Professor Marilyn Anderson of the La Trobe Institute of Molecular Science, La Trobe University have recently been awarded the biennial Ramaciotti Biomedical Research Award worth \$1 million to advance their research into the use of plants to deliver medicines.

The Ramaciotti Biomedical Research Awards are highly contested and traditionally focus on projects that have enormous benefit to society but would find it difficult to attract funding from conventional sources. Professors Craik and Anderson's research focusses on the use of a type of plant protein known as a cyclotide, to facilitate the delivery of medicines through the consumption of the plant. As the commercial model for this type of product is difficult to define, it would have had difficulty attracting other more commercial grants. To date, the Professors have chemically re-engineered certain cyclotides to develop therapies that may treat multiple sclerosis, cardiovascular disease, cancer and chronic pain.

The benefits of this research to developing countries are obvious; plants that deliver medicinal benefits can be locally grown and harvested for consumption as food or as teas, overcoming transportation, storage and economic issues. However, the Professors believe their research may also have important applications in developed countries; that by manipulating plant proteins they may be able to develop therapies that have fewer side effects and are effective in difficult to treat conditions.

A potential application of this research is delivering anti-HIV medicine to developing countries. In many African nations, HIV/AIDS remains a leading cause of premature death and the associated morbidity and mortality has significant societal impacts. In this instance the problem isn't the existence of effective medicines, but that cost and logistical issues prevent the medicines from reaching the people who need them. Another application is developing molecules to treat chronic pain, as current therapies are only effective in some patients. Professors Craik and Anderson's research has uncovered a molecule that may be significantly more effective than morphine, a potentially significant benefit to chronic pain sufferers.

If the research delivers on its promise, the benefits to society will be enormous and prove to be a valuable contributor to the wider drug development programme. Currently it is expected that human trials of these compounds will begin in the next decade.

### About the Ramaciotti Biomedical Research Award

This is a \$1 million grant awarded every two years to fund biomedical research that would otherwise find it difficult to attract funding. Being a highly contested and prestigious award, the selection of the winner is made by a scientific advisory committee. The funding for the award is provided by the Ramaciotti Foundation, which was established in 1970 and has since then provided grants of close to \$56 million for biomedical research, making it one of the largest privately funded contributors to biomedical research.

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# matters

# Medicinal cannabis

### **Bridin Murnion**

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#### Key words

cannabidiol, drug regulation, medical marijuana, nabiximols

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### SUMMARY

A number of therapeutic uses of cannabis and its derivatives have been postulated from preclinical investigations.

Possible clinical indications include spasticity and pain in multiple sclerosis, cancer-associated nausea and vomiting, cancer pain and HIV neuropathy. However, evidence is limited, may reflect subjective rather than objective outcomes, and is not conclusive.

Controversies lie in how to produce, supply and administer cannabinoid products. Introduction of cannabinoids therapeutically should be supported by a regulatory and educational framework that minimises the risk of harm to patients and the community. The Regulator of Medicinal Cannabis Bill 2014 is under <u>consideration</u> in Australia to address this.

Nabiximols is the only cannabinoid on the Australian Register of Therapeutic Goods at present, although cannabidiol has been recommended for inclusion in Schedule 4.

### Introduction

The intoxicating properties of cannabis have been recognised for millennia. The major psychoactive constituent of cannabis is  $\Delta$ -9-tetrahydrocannabinol (THC). The non-psychoactive cannabidiol is another major component. Characterisation of these and other derivatives, as well as the receptors they interact with, has increased our understanding of the endocannabinoid system.<sup>1</sup>

Evidence from animal studies has supported a role for cannabis derivatives and endocannabinoids in acute, visceral and cancer pain, neuro-inflammatory and neurodegenerative disorders, appetite and weight gain, cancer, seizure disorder and inflammatory bowel disease.<sup>2</sup> This has led to clinical studies of cannabis.

It is imperative that debate around medicinal cannabis use is not confused with legalisation of recreational marijuana.

### **Cannabis products**

There is no agreed definition of medicinal cannabis. The term is used to refer to the therapeutic use of herbal cannabis and its constituents. Nabiximols is the only medicinal cannabis included on the Australian Register of Therapeutic Goods (ARTG). It is a combination of cannabidiol and THC in a spray, indicated for muscle relaxation for spasticity in multiple sclerosis. Nabiximols is a Schedule 8 drug. Cannabidiol has been recommended for inclusion in Schedule 4.<sup>3</sup>

Nabiximols is also available overseas along with other cannabis products including:<sup>4</sup>

- nabilone a synthetic derivative of THC
- dronabinol synthetic THC
- cannabidiol
- oral cannabis extract
- herbal medicinal cannabis with defined amounts of cannabidiol and THC
- unregulated cannabis.

In the Netherlands, the Office for Medicinal Cannabis oversees production of pharmaceutical grade herbal cannabis. Different strains of cannabis are cultivated under stringent conditions with strict quality control to produce herbal cannabis with variable but defined amounts of THC and cannabidiol.<sup>5,6</sup> This is distributed through pharmacies and is supported by patient information.<sup>5</sup>

### Pharmacology of THC and cannabidiol

The most studied cannabinoids are THC and cannabidiol. THC is the major psychoactive constituent of cannabis and acts as a partial agonist at CB1 and CB2 receptors.<sup>7</sup> Cannabidiol is not psychoactive and is an antagonist at CB1 and CB2.<sup>8</sup> It acts at multiple other receptors and can be an agonist in some systems.

Cannabidiol reduces the psychoactive effect of THC, improving its tolerability and, perhaps also, its safety by reducing the likelihood of adverse psychiatric effects. Cannabis also contains other less well characterised phytocannabinoids. Metabolites of parent compounds may also have activity.<sup>7,9</sup>

### The endocannabinoid system

The endocannabinoid system is complex and has numerous physiological roles including immunomodulation, neuroplasticity, learning, emotional modulation, motivation, appetite, vascular function and gut motility.<sup>10</sup>

The cannabinoid receptors – CB1 and CB2 – are predominantly inhibitory.<sup>9,10</sup> CB1 is mainly located in the central and peripheral nervous systems, altering neurotransmitter release, and CB2 on immune cells, modifying cytokine release.

### Animal models of disease

A role for cannabinoid receptor modulation has been suggested in a number of diseases.<sup>2,7</sup> In animal studies, CB1 receptor activation reduced nausea and vomiting, and increased feeding. It also reduced seizures and nociception in visceral pain. Reduction of intraocular pressure has also been demonstrated. Activation of the CB1 receptor may enhance survival in haemorrhagic and cardiogenic shock. Animal studies have also shown that activation of CB1 and CB2 receptors may reduce the clinical manifestations of multiple sclerosis, neuropathic and inflammatory pain, and reduce tumour cell growth and angiogenesis in some cancers. CB2 receptor activation reduces inflammation and progression of atherosclerosis, and increases apoptosis.<sup>2</sup>

### **Clinical applications**

Cannabis has been trialled for various indications.

#### Multiple sclerosis

The American Academy of Neurology has developed a consensus statement on the use of cannabinoids for multiple sclerosis. Evidence supports oral cannabis extract, THC and nabiximols for subjective, but not objective, improvements in spasticity. Oral cannabis extract reduces central pain in multiple sclerosis, while THC and nabiximols are probably effective. The efficacy of smoked cannabis in either spasticity or central pain is unclear.<sup>11</sup>

### HIV

A modest benefit of dronabinol has been shown in HIV-associated weight loss. However, robust data in patients receiving highly active antiretroviral therapy are not available.<sup>12</sup> In HIV neuropathy, smoked cannabis reduces pain, including experimentally induced pain, when assessed by changes in visual analogue scores.<sup>13</sup>

#### Chronic non-cancer pain

While cannabis and derivatives show some efficacy in pain associated with multiple sclerosis, cancer and HIV, evidence in other painful conditions is inconclusive. In patients with rheumatoid arthritis, there may be a minor effect on pain.<sup>13</sup> Evidence for efficacy of cannabinoids in fibromyalgia is limited.<sup>13</sup>

Overall, medicinal cannabis is not recommended in chronic non-cancer pain. Indeed its psychoactive effects may cause poor engagement in multimodal, nonpharmacological pain management.<sup>14</sup>

### Cancer

The US National Cancer Institute reports evidence for the use of nabiximols, nabilone and cannabis in cancer-related pain.<sup>15</sup> Cancer Council Australia's position statement similarly acknowledges some benefit in pain, appetite stimulation and nausea.<sup>16</sup> Nabilone and dronabinol are approved in Europe and the USA for cancerrelated vomiting. There is not adequate evidence for inhaled cannabis in this indication.<sup>15</sup>

### Epilepsy

There are mixed data in animal models of epilepsy. THC has been shown to be both pro- and anticonvulsant. Cannabidiol appears more promising, with some limited experience in humans.<sup>17</sup> Preliminary data from a trial of cannabidiol (Epidiolex) found benefit in treatment-resistant paediatric epilepsy.<sup>18</sup> This has led to much community debate, and to parents accessing cannabinoids illegally for treatment of children with catastrophic epilepsy syndromes.<sup>19</sup>

#### Cannabis withdrawal

Recent data show that nabiximols reduces symptoms during cannabis withdrawal, but does not impact on long-term outcomes.<sup>20</sup>

### Neurodegenerative disorders

The antioxidant and anti-inflammatory properties of cannabidiol have led to investigation of cannabinoids in neurodegenerative disorders including Huntington's disease, Parkinson's disease and neonatal hypoxiaischaemia. No definitive role has been identified.<sup>8</sup>

#### Appetite suppression

Rimonabant, a CB1 receptor inverse agonist\*, was available briefly for appetite suppression. However, it was withdrawn due to psychiatric adverse effects.<sup>21</sup>

### **Toxicities**

The psychoactive effects of cannabis include anxiety, dysphoria, euphoria, hallucinations, paranoia, acute memory impairment and reduced cognitive performance. Acute cannabis use is also associated with increased motor vehicle accidents.<sup>22</sup>

Increased airway diseases and oropharyngeal cancers may be risks of smoking cannabis. Other chronic toxicities include dependence, increased risk of schizophrenia and, probably, cognitive impairment.<sup>22</sup>

In clinical trials, discontinuations because of adverse effects were predominantly in response to psychiatric events. These were associated with higher doses of THC,<sup>11</sup> and were less common at higher doses of cannabidiol.<sup>5</sup> Notably, in a number of American states where medical cannabis laws have been enacted, there is a reduction in overdose deaths from opioids.<sup>23</sup>

### Challenges

There are many challenges in considering medicinal cannabis.<sup>24</sup> Evidence supports the use of medicinal cannabis in a small number of conditions, but there is significant community pressure for use beyond these conditions.

The complexity of endocannabinoid signalling and the multiple receptor targets of cannabinoids present challenges when developing compounds with predictable efficacy and toxicity.<sup>8,25</sup> Ideally, medicines are provided as refined molecules with defined pharmacology, accurate dosing, minimal adverse effects and optimal efficacy. However, it may be that therapeutic benefits are effected by the mixture of compounds in herbal cannabis, rather than by the isolated cannabinoid.

Diversion of medicinal cannabis is of concern, as is early initiation of use in adolescents. There is also the risk of accidental childhood overdose.<sup>24</sup>

Canadian guidelines for cannabis 'prescribing' recognise that treatment with herbal cannabis is not a prescription per se, and suggest various methods for improving safety.<sup>26,27</sup>

As in all therapeutic decisions, the principles of the quality use of medicines should be followed. These include considering if a medicine is needed and, if so, choosing one that is safe and effective in the correct formulation and dose.<sup>28</sup>

In general, smoking herbal cannabis is not recommended. Vaporising or ingestion of herbal product is purportedly safer, but dosing remains inaccurate and bioavailability variable.<sup>4,5</sup>

A harm-benefit assessment is critical in decision making. In terminal disease or intractable epilepsy, using products or delivery routes that might otherwise be unacceptable may be supported.

### Regulation

Legislation around medicinal cannabis is complex and evolving. Products listed on the ARTG are governed by the *Therapeutic Goods Act 1989*.<sup>29</sup> *The Narcotic Drugs Act 1967* regulates narcotic cultivation and production.<sup>30</sup> The Regulator of Medicinal Cannabis Bill 2014 is currently under consideration by the Australian Government.<sup>31</sup> This bill, if enacted, would provide a system for regulating cannabis independent of the Therapeutic Goods Administration, and a system for cannabis cultivation and production parallel to the Narcotic Drugs Act.<sup>31</sup> Development of such a regulatory system will likely be costly.

If medicinal cannabis is to be introduced, it should be supported with prescriber and consumer education, prescriber peer review, a robust authority process and pharmacovigilance for adverse events. Hopefully we can prevent the emergence of the problems seen with prescription opioids and benzodiazepines. The regulatory framework must be responsive to changes in evidenced-based practice.

\* An inverse agonist binds to a receptor but has the opposite effect of an agonist.

# matters

### Conclusion

There is some evidence of therapeutic benefit for cannabis products in defined patient populations. While waiting for a regulatory framework, more defined products, and more definitive data to become available, a major question is whether herbal cannabis should be introduced, with appropriate legislation to prevent criminalisation, for strictly defined populations and diseases. Monitoring for individual and community safety should be a component of any model.

Conflict of interest: none declared

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### PSA, MIMS Victorian Intern Pharmacist of the Year 2015



# Congratulations to a young leader and deserving winner

The Intern Pharmacist of the Year award is judged on the nominees' display of leadership and initiative in service delivery, their commitment to patient care and the safe use of medicines, and their peer and professional engagement throughout their internship year. The winners over the last five years have been exemplary and a great addition to their profession.

The 2015 Intern of the Year is awarded to **Xavier Agostino.** 

Xavier completed his internship at MyChemist Northland.

Prior to commencing his internship, Xavier had already held a number of key leadership positions, including representing over 3,500 pharmacy students as the president of NAPSA. Throughout his internship year Xavier further developed his leadership skills, influencing students and other health professionals to achieve best practice within our industry. Earlier this year, he was invited to join the APC's Accreditation Committee, and he has also written opinion articles for the AJP. During his internship, Xavier has been proactively identifying patients with poor medicine adherence and contacting their doctors to discuss options in their medicine regime, to ensure safe use, better compliance and overall improved health outcomes. As an intern, he also established a fall prevention promotional program in the pharmacy. It was such a success that a number of elderly patients were taken off their benzodiazepines by their doctors.

Linda Nguyen, his preceptor at MyChemist Northland said that Xavier does not settle for anything less than best practice standards. She regards him as the most inspiring intern that she has ever worked with, and has no doubt that he will continue to grow and develop into one of the best pharmacists within the profession.

The award was presented at the PSA dinner on Friday November 23rd. Xavier will now join the other State finalists at PSA16 where the national winner will be announced.

### Health Informatics and the CHIA program



Electronic management of health information in Australia is becoming more widespread, which brings with it huge potential for improving patient safety and reducing healthcare costs. On the flip side, high expectations have not been fully met and there are several reports of failed (and very expensive) projects. There is great value in having skilled people working in e-health who have a deep understanding of the needs of clinicians, information technology professionals and healthcare administrators. In line with this, the MIMS Clinical Innovation team was formed at the beginning of 2015 with a main focus of understanding the workflow of healthcare professionals in the digital environment, especially with regards to electronic medications management.

The team is made up of a diverse mix of clinicians, clinical information editors and information technology professionals. As a newly formed and very enthusiastic group, we were keen to expand our knowledge of health informatics and create a solid foundation from the expertise we already had. Formal recognition was also a bonus, so we set ourselves the goal of obtaining the Certified Health Informaticians Australasia (CHIA) credential.

The CHIA program was developed by the Health Informatics Society of Australia (HISA), the Australasian College of Health Informatics (ACHI), and the Health Information Management Association of Australia (HIMAA). It was designed to provide an assurance of competence, that those who gain the credential have requisite knowledge and skills to perform safely and effectively in health informatics and e-health, both nationally and internationally.

The certification covers a wide range of competencies that are organised into the following broad yet interrelated categories:

- Information and Communications
  Technology
- Health and Biomedical Science
- Information Sciences
- Management Sciences
- Core Principles and Methods
- Human and Social Context

Upon registering for the program, a study guide is provided with suggested reading materials for each of the competencies. Certification is then gained by passing an online exam which tests these competencies at three different levels of expertise: knowledge, comprehension and application.

MIMS is pleased to announce that one of our team members recently achieved the goal of earning the CHIA credential, with the rest planning to follow suit in the coming months.

For further information about the CHIA program, please contact HISA on 03 9326 3311 or by emailing certification@hisa.org.au. If you would like to get in touch with the MIMS team regarding e-health, please contact the team manager: Gillian.Swannick@mims.com.au.

# amatters

Bp Summit fueled by learning, fun and laughter The 2015 Bp summit was held at Sea World Resort on the Gold Coast. The Bp summit is the official user event and conference, and since its inception, delegate numbers have gown each year. 2015 was no exception, with delegates from both the clinical and practice management areas of health. At the summit, executives, leaders and product experts met with Bp users, showcased their products, provided user workshops, answered user questions and listened to feedback.

MIMS and Bp have been partners for many years but this was MIMS' first visit to the summit and the interaction between the team from Bp and their customers was impressive. It was not all work, with a highlight being the amazing gala dinner held at Movie World. Entertainment was provided by stars of stage and screen and brave delegates rode multiple amusement park rides.

It has been a big year for Bp; they have (to name a few achievements) opened new offices in Australia and NZ, increased staff and formed a Clinical Leadership Advisory Committee. To learn more about Bp products, both in Australia and New Zealand you can visit their website bpsoftware.com.au.

Thank you Bp for a great few days and the chance to talk with many of your customers.



### GP15 - Our future in practice



Our future in practice was the overarching theme of this year's RACGP Conference for General Practice held in Melbourne. It was a busy few days with delegates exploring themes and topics designed to "inspire and encourage you to consider your future in practice, and the impact on your patients and communities."

Discussions focused on ensuring that general practice remains at the centre of the Australian healthcare system through GP-led coordinated care; how technologies and business structures can be used to improve the efficiencies and effectiveness of a practice, and developing skills and knowledge to improve the outcomes for your practice, patients and community.

MIMS exhibited again this year and our focus was on both our own reference products (eMIMSCloud and iMIMS) and our MIMS Integrated partners, many of whom were also exhibiting.

• The Zedmed team were busy and giving away Fit Bits - standing by their healthy tweets over the last few months. They also announced their partnership with Jayex, where the Jayex Patient Self Check-in systems will be integrated into Zedmed practice management software.

- There was a real buzz about the Medtech booth, where they bought along a Police Box Time Machine to launch their newest software product, Medtech Evolution. They used this setup to promote the idea that 'Now every doctor can be a Time Lord' with Medtech Evolution 'the galaxy's most time efficient, fully integrated clinical and practice management system.'
- The Best Practice team were constantly occupied with doctors wanting information about Bp's plans for VIPgold and VIP. net, both added to the Bp software range this year. 2015 has been a huge for Bp with the successful summit, the purchase of VIP and the opening of new offices in Brisbane, Sydney and New Zealand.
- Telstra Health, one of our new MI partners was also exhibiting with their focus on CloudMed's Clarity, which is used by Telstra Health's ReadyCare team here in Australia. CloudMed also partners MIMS in South East Asia and Malaysia.

### Hospital & Health



Conference: 12th Health Libraries Inc., State Library of Victoria

MIMS recently participated at the 12th Health Libraries Inc. conference at the State Library of Victoria.

The conference attendees were a dynamic group of information professionals committed to health information provision, resource sharing, professional development and relevance to the community.

With the conference program featuring a number of streams and a multi-sector focus, MIMS was able to take part in several discussions. These discussions provided us with valuable insight that will help us in optimising our service to current users and in designing future applications and services.

Topics of particular interest to us here at MIMS included the library systematic reviews - hints,

tricks and what you need to know to make a real difference, and the rapid expansion of cloud based delivery and evidence based resources. We also discussed the importance of relevant and focused quality content, delivered at optimal depth at the right time and in the right place – often directly into the user's professional workflow.

With fellow delegates from public and private health sectors and higher education institutions in Australia, it was the perfect opportunity for us to meet face to face with our customers and friends. Throughout the day we met with various users of our digital reference and integrated knowledge resources. They all shared plenty of valuable feedback and suggestions that will definitely guide us in our aim of delivering the most comprehensive, innovative and flexible medicines knowledge and clinical decision support.

### Thank you

As we approach the last few weeks of 2015, the team at MIMS would like to thank all our subscribers, partners and users for their ongoing support. Delivering an updated medicines database every month for the last 52 years is no easy task, but it is one that we feel extremely privileged to be able to provide.

As the saying goes, "the only constant in life is change" and healthcare and medicines information are no exception to this. Through the MIMS Innovations Team, we have worked closely with our users and partners this year to be able to anticipate upcoming needs. In 2016 we hope that you start to see some of the results of this work, which is ongoing.

Thank you for your continued support during this year – it is only through the feedback and close working relationships that we have with our users, that MIMS is able to continue to provide and develop the products that we think are important to support the healthcare community.

Wishing you all a happy, healthy and safe Christmas and a good start to 2016.

The team at MIMS

# Wishing you a Happy Christmas and a healthy & prosperous New Year



To thank you for utilising MIMS' unparalleled body of medicines knowledge throughout 2015 we knitted you a pillover!

# matters

# MIMS Staff Profile



Marissa Pui Editor

### What is your role at MIMS?

My role as an editor at MIMS involves preparing, updating, reviewing and maintaining product information for the MIMS database. The editorial team work together to ensure that all content within our database is accurate and up to date for use by our software vendors and subscribers.

### What is your background?

I have a Bachelor of Commerce from the University of New South Wales and a Bachelor of Pharmacy (Honours) from the University of Sydney. Prior to my pharmacy degree I was an accountant at a medium sized graphic design agency. I worked in community pharmacy throughout both degrees and completed my internship at Royal North Shore Hospital last year to become a registered pharmacist in early 2015. I joined the MIMS team in June 2015.

# What do you enjoy most about your role?

I enjoy working within a team of likeminded people to deliver highly accurate, useable medical information. Reading product information every day allows me to constantly increase my breadth of knowledge and to keep up to date with new products and therapies coming onto the market. Within our team we have editors from all different backgrounds and its great to be able to share ideas and continue to learn from each other.

# What do you enjoy outside of the office?

I love to travel and am looking forward to my next trip to New York and LA, then the beautiful ski fields of Japan. I've been a skier since I was young but am now determined to learn to snowboard, and I can think of no better place in the world to learn! I love being immersed in new cultures and getting lost in new cities, but most of all I love to try all the weird and wonderful food that these places have to offer. Closer to home I enjoy being with family and friends sharing good food, drink and music, or lazing around in the sun by the beach.

# Upcoming Conferences

### APP 2016

- The Pharmacy Guild of Australia's Annual National Conference Thursday 17th to Sunday 20th March 2016 Gold Coast Convention & Exhibition Centre, Broadbeach, QLD www.appconference.com



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