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Health

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- 15 February 2016 - Applications close - Health Promotion Innovation Fund - http://www.health.act.gov.au/healthy-living/health-promotion-grants-program

Produced by ACT Health, Population Health Division

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Introduction

A message from the Chief Health Officer, Dr Paul Kelly

Pharmaceutical regulation is an important task for the Chief Health Officer (CHO) in every Australian jurisdiction. In the ACT, this role is defined in the *Medicines, Poisons and Therapeutic Goods Act 2008* and related Regulations. These in turn are closely aligned to federal laws related to drug and poisons scheduling and the licensing, safety and effectiveness of therapeutic goods, as well as with the ACT justice system and with clinical services.

The role of the CHO is in balancing the individual and public health harms and benefits which can arise from the use of pharmaceutical substances. These can be divided into three main areas: monitoring the use of medications, in particular controlled drugs such as narcotics and amphetamines; monitoring, regulating and analysing the use of recreational drugs, especially novel substances; and the regulation of pharmacies and pharmacists in the ACT, including the exploration of expanded roles for pharmacists, such as health promotion and as vaccination providers. Each of these topics is covered in this Issue of the Bulletin.

In addition to these routine roles, the CHO is commonly requested to offer advice on emerging regulatory issues. Two recent ACT examples are medical marijuana and kava.

Medical marijuana remains a very topical issue with strong proponents on both sides of the debate. Our role is to offer a balanced view of the population health benefits and risks of any suggested scheme to allow the use of cannabis as a therapeutic agent for particular diseases and conditions. The article in this Issue of the Bulletin outlines the range of potentially therapeutic ingredients contained in the cannabis plant, the current regulatory controls in Australia and what can be learnt from other countries who have introduced various schemes. As this Issue goes to press, the ACT Government continues to consider a local response, whilst closely monitoring developments nationally and in other jurisdictions.

Kava is a plant native to the Pacific which has been widely used by Pacific Islanders for ceremonial purposes for many centuries. It has also been associated with toxic effects, particularly when consumed in large amounts. For this reason, at the national level, kava has been classified as a prescription-only drug and therefore its use is restricted. There is clearly a role for a risk-based regulator to assess the balance of the cultural importance of kava to the ACT Pacific Islander community, whilst taking account of the potential for wider public health risk. The way in which potentially conflicting policy positions have been resolved in the ACT over the past four years is described in this Issue.

Thanks to our Guest Editor, Adam Duffy and to all the authors who contributed to this Issue.

Dr Paul Kelly
ACT Chief Health Officer
November 2015

Breaking News

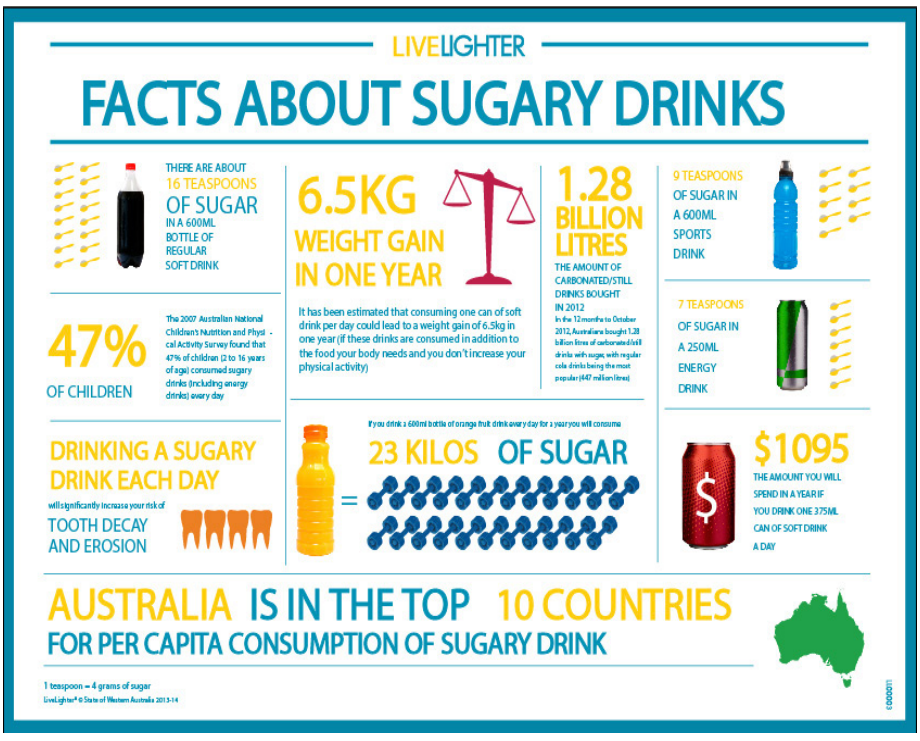
New phase of the LiveLighter® campaign highlights the health risks of sugary drinks

On 8 October 2015 the ACT Chief Health Officer, Dr Paul Kelly, launched a new six week phase of the LiveLighter® campaign, highlighting the serious health effects of regular sugary drink consumption. The aim of the new phase of the LiveLighter® campaign is to show that drinking sugary drinks contributes not only to weight gain, but to chronic medical issues, such as heart disease, type 2 diabetes and some cancers.

Image: Campaign Images. LiveLighter®. Heart Foundation ACT

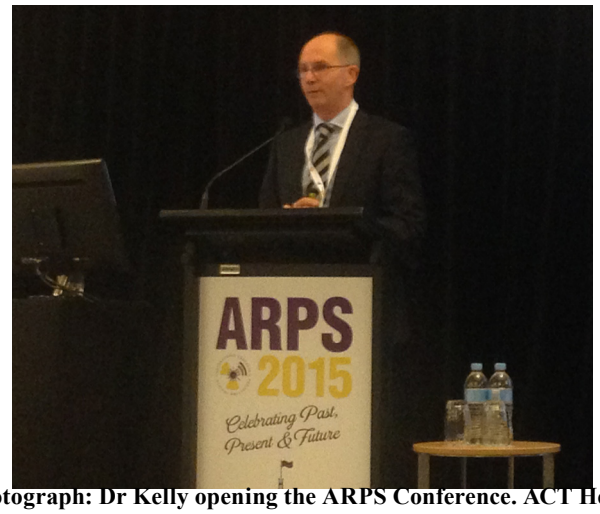
The new campaign depicts a man reaching for a sugary drink from a fridge in a convenience store. The camera then takes the viewer inside the man's body for a graphic look at the 'toxic fat' surrounding his vital organs. According to the Australian Bureau of Statistics, sugary drinks are a regular feature in the diets of many Australians. A third of Australians consume sugary drinks on any given day, containing an average of 13 teaspoons, or 54 grams, of sugar.

LiveLighter® is delivered by the Heart Foundation ACT, and is funded by the ACT Government through the ACT health promotion grants program. For more information visit http://www.livelighter.com.au/



2015 Australasian Radiation Protection Society Conference held in Canberra

The ACT Chief Health Officer, Dr Paul Kelly, officially opened the 2015 Australasian Radiation Protection Society (ARPS) conference that was held in Canberra between 6 and 9 October.



Photograph: Dr Kelly opening the ARPS Conference. ACT Health

The conference marked the 40th anniversary of the society in Australia. Over 120 delegates from across Australia and around the world attended the conference to hear a variety of presentations compiled around the conference theme of 'Celebrating Past, Present and Future'.

During his opening address Dr Kelly spoke about his role as Chief Health Officer and associated public health responsibilities, including radiation protection. Dr Kelly also highlighted the parallels between radiation protection and other public health concerns. Dr Kelly noted that risk communication is key to ensuring public health messages are understood, and introduced the audience to Peter Sandman's concept that "Risk = Hazard + Outrage".

The conference highlighted new developments in radiation protection and showcased innovations of the past. Over three days presentations were held on a wide range topics including medical applications of radiation including medical imaging and radiation therapy; mining and environmental radiation; non-ionising radiation sources including Wi-Fi and hair removal lasers; and risk communication and emergency response.

Keynote presentations at the conference included:

- Professor Barry Brooks from the University of Tasmania spoke on nuclear energy solutions for the future;
- Emilio Garcia Neri from the Spanish National Agency for Radioactive Waste Management and Decommissioning spoke about the El Cabril radioactive waste storage facility in Spain;
- Dr Paul Cardew presented a historical perspective on radiation protection achievements in Australia; and
- Professor Pete Cole from the UK Society for Radiological Protection spoke on the society's innovative new programs, including a schools outreach program.

For information on radiation protection in the ACT visit www.health.act.gov.au/radiationsafety or contact the Health Protection Service HPS@act.gov.au

Breaking News

Healthy Canberra Forum

The ACT Minister for Health, Simon Corbell MLA, opened the Healthy Canberra Forum at the National Convention Centre on 13 October 2015. The forum encouraged discussion on the issue of overweight and obesity with key stakeholders including non-government partners. In addition, the forum was an opportunity to showcase the recent progress and upcoming priorities of the ACT Government's Healthy Weight Initiative. The forum marks the two year anniversary of the launch of the ACT Government's Towards Zero Growth: Healthy Weight Action Plan. The Action Plan set the target of "zero growth" in the rates of overweight and obesity within the ACT.

Photograph: ACT Minister for Health, Simon Corbell. ACT Government

"While we know the Healthy Weight Initiative has achieved great inroads so far, we still know that almost two thirds of ACT adults are overweight and one in four is obese. The ACT Government remains committed to delivering on a healthy, active and vibrant Canberra and will continue to deliver on the priorities of the Healthy Weight Initiative," Mr Corbell said.

The guest speaker for the forum was the Professor of Population Nutrition and Global Health, Boyd Swinburn from the University of Auckland. Professor Swinburn is also the Director of the World Health Organization (WHO) Collaborating Centre for Obesity Prevention at Deakin University in Melbourne. Professor Swinburn provided an overview on obesity prevention in Australia and internationally.

Professor Swinburn said the ACT was in an excellent position to lead on obesity prevention. Its relatively small size, educated population, and government commitment provides the ACT Government's Healthy Weight Initiative a number of opportunities to make its efforts in obesity prevention a serious legacy.

To access the twitter discussion from the Healthy Canberra Forum, please go to: https://twitter.com/search?q=%23healthycbrforum&src=typd. Alternatively for further information on the Healthy Weight Initiative, please go to: www.act.gov.au/healthyliving.

Acronyms and Resources

Acronyms

ACCS	Advisory Committee on Chemicals Scheduling
ACMS	Advisory Committee on Medicines Scheduling
ACTAS	ACT Ambulance Service
ACTINOS	ACT Investigation of Novel Substances
ADHD	Attention deficit hyperactivity disorder
AHPRA	Australian Health Practitioner Regulation Agency
AIDS	Acquired Immunodeficiency Syndrome
AHMAC	Australian Health Ministers Advisory Council
ARPS	Australasian Radiation Protection Society
BOM	Bureau of Meteorology
CBD	Cannabidiol
CHO	Chief Health Officer
DAPIS	Drugs and Poisons Information System
DoH	Department of Health
ERRCD	Electronic Recording and Reporting of Controlled Drugs
FMIG	Food-Medicine Interface Guidance Tool
FSANZ	Food Standards Australia New Zealand
HPS	Health Protection Service
ISFR	Implementation Sub-committee for Food Regulation
MAC	Medicines Advisory Committee
MPTG	*Medicines, Poisons and Therapeutic Goods Act 2008*
NCEPH	National Centre for Epidemiology and Population health
NPSs	Novel psychoactive substances
NRAS	National Registration and Accreditation Scheme
PBA	Pharmacy Board of Australia
PSA	Pharmaceutical Society of Australia
QPIP	Queensland Pharmacist Immunisation Pilot
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TGA	Therapeutic Goods Administration
THC	Δ9-tetrahydrocannabinol
WHO	World Health Organization

Resources

- Health Protection Service - http://www.health.act.gov.au/public-information/public-health/health-protection-service
- ACT Health Promotion Grants - http://www.health.act.gov.au/healthy-living/health-promotion-grants-program
- ACT Legislation Register - http://www.legislation.act.gov.au/default.asp
- Therapeutic Goods Administration - https://www.tga.gov.au/
- National Drug Strategy - http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/publishing.nsf/Content/framework-lp Pharm Framework
- National Pharmaceutical Drug Misuse: Framework for Action 2012-2015 - http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/publishing.nsf/Content/drug-mu-frm-action
- Standard for the Uniform Scheduling of Medicines and Poisons - https://www.tga.gov.au/publication/poisons-standard-susmp
- Pharmacy Board of Australia - http://www.pharmacyboard.gov.au/
- Pharmacy Guild of Australia - http://guild.org.au/
- Pharmaceutical Society of Australia - https://www.psa.org.au/

Challenges in medicines regulation

Adam Duffy, Pharmaceutical Services Section, Population Health Division

The regulation of medicines in Australia is fundamental to our healthcare system to ensure that therapeutic treatments are both safe and appropriate for use. It is a critical and complex process that must take into account the needs of patients to access medicines against the potential public health consequences of medicine misuse. Without balanced regulation, medicines can have significant individual health and community costs through various issues such as further illness, overdose, addiction, lost productivity and death.

To manage the regulatory challenges of medicines in Australia, all states and territories refer to the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) to help regulate who, how and when a person may access a particular medicine. In the ACT, the *Medicines, Poisons and Therapeutic Goods Act 2008* (MPTG Act) principally governs the sale, supply and safe use of medicines.

Why regulate medicines?

The idea that medicines can both benefit and harm has been well known for centuries. The ancient Greek word "pharmakon" is a classic example of this paradoxical relationship with medicines which can be interpreted as both 'remedy' and 'poison'. While taking medicine is generally synonymous with improved health outcomes, all medicines have the potential to cause harm.[1]

While eliminating all risks and harms of medicines is not realistically achievable, the public health risks can be minimised through regulation and educational efforts. In Australia, the availability and use of medicines are subject to strict regulation to ensure that they remain safe and effective. Without regulatory oversight, there is the risk that medicines may be used incorrectly or inappropriately, which can lead to unfavourable consequences, such as addiction, hospitalisation, drug resistance further illness or even death.[1]

Many countries, including Australia, tightened their regulatory controls over the use and availability of medicines as a result of the thalidomide tragedy of the early 1960s. Thalidomide (used by expectant mothers as a treatment for morning sickness) caused severe birth defects in newborns, most characteristically limb malformation.[2] Around 40 percent of these children died within 12 months of birth and many others suffered lifelong disability.[3]

The thalidomide incident prompted the world to bolster medicine safety through regulation. While increased regulatory efforts and education campaigns have largely eliminated medicine disasters like this one, medicine misuse continues to be an emerging societal issue. The abuse, misuse and diversion of medicines has serious implications for the ACT community through individual health, social and economic costs.[4,5,6]

Photograph: Child affected by Thalidomide. Public Domain

How are medicines regulated?

It is critical that medicines are regulated in order to minimise related morbidity and mortality. The Therapeutic Goods Administration performs a critical role in ensuring that available medicines are assessed for safety and efficacy. However the use of medicines is ultimately subject to state and territory legislation.

In the ACT, medicines are regulated through various mechanisms such as licences and permits under the MPTG Act. The Chief Health Officer aims to minimise any misadventure with medicines and poisons through administering the regulatory functions under the MPTG Act and the Medicines Poisons and Therapeutic Goods Regulation 2008.[7]

The ACT undertakes a risk-based approach to regulation of medicines. A particular medicine may be subject to a variety of conditions, restrictions or otherwise prohibited depending on its risk. The risk of a particular substance is broadly determined by its scheduling status under the Commonwealth Poisons Standard.[8]

The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), otherwise known as the Poisons Standard, classes medicines and poisons into schedules and appendices for regulatory purposes. The SUSMP also provides recommendations on the labelling and packaging of regulated substances. The Secretary of the Department of Health has responsibility for listing medicines and poisons under the SUSMP's schedules. The ten schedules of the SUSMP can be viewed at www.commlaw.gov.au.[8]

The ACT recognises the SUSMP's schedules under the MPTG Act to provide for a consistent approach as to when, who and how a medicine might be used. The SUSMP lists substances under schedules according to the degree of recommended control over their availability.[8,9] For example, Schedule 10 substances (e.g lead) are of such danger they are prohibited from sale, supply and use, whereas a Schedule 4 (prescription only) medicine may be available to a person on prescription.

The SUSMP has allowed all states and territories to regulate medicines in a consistent fashion.

Balanced regulation

There is often a public expectation that medicines should both be easily accessible, but also suitably restricted in order to prevent undue health and social costs.[10] State and territory governments are faced with the difficult challenge of balancing the needs of patients to use medicines against the potential public health risks of allowing access to a potentially hazardous substance.

Despite increased efforts at both national and local levels to achieve this delicate policy balance, the public health consequences of medicines misuse and abuse continue to increase at both local and national levels. The National Pharmaceutical Drug Misuse: Framework for Action 2012-2015 reports that Australia is experiencing a trend toward prescription medicine abuse, misuse and diversion. The types of medicines implicated in misuse are typically found under Schedule 8 of the SUSMP (controlled drugs) e.g. morphine, oxycodone, amphetamines and alprazolam.[6]

Opioid analgesic medicines (painkillers) are now subject to a greater rate of abuse than even some illicit substances with some painkillers such as oxycodone gaining notoriety as "hill-billy heroin".[11] In 1998-99 prescription opioid medicines accounted for 33 percent of hospital opioid poisonings in Australia. This figure grew to 80 percent by 2007-08 to far exceed the number of hospital admissions for heroin poisoning.[5]

Challenges in medicines regulation

The policy challenges around medicines regulation are not unique to the ACT or Australia. The misuse of medicines is a global issue that is frequently highlighted in the media when associated with impropriety or premature death. For example medicine regulation made global news headlines following the untimely deaths of celebrities like Heath Ledger, Anna Nicole Smith and Michael Jackson.[12]

Recognising the complexities of medicines regulation, in 2014 ACT Health implemented the Drugs and Poisons Information System (DAPIS) to collect information each week about all controlled medicines dispensed across ACT pharmacies. The ACT's DAPIS is modelled on Tasmania's controlled drug monitoring system and has already vastly improved the ACT's ability to monitor and regulate controlled medicines. Information from the DAPIS is also being used to develop policy changes around controlled medicines regulation with a view to streamlining existing processes and improving public health outcomes.

The ACT continues to work with all jurisdictions to minimise medicine related public health risks through smart, flexible and evidence based solutions like the DAPIS program.

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Medicines Scheduling

Medicines and poisons scheduling has its origins in the 19th Century, when concerns over accidental and deliberate poisonings led to tighter access controls. In those days, the chemicals industry was in its infancy and dangerous chemicals were often available from pharmacies, grocery and produce stores.

In Australia, public access to medicines and poisons is largely controlled through a national scheduling system, based upon a risk profile for the substance. Scheduling restrictions can apply to a range of substances, including medicines for human therapeutic use, veterinary, agricultural, domestic and industrial chemicals. Scheduled substances are listed in the Standard for Uniform Scheduling of Medicines and Poisons (SUSMP), under the Commonwealth *Therapeutic Goods Act 1989*. The Poisons Standard is adopted in states and territories to varying extents under respective medicines and poisons legislation, with corresponding controls around possession and supply. In the ACT, the Poisons Standard is adopted in its entirety under the *Medicines, Poisons and Therapeutic Goods Act 2008.*

The schedules

The Poisons Standard classifies substances into 10 schedules as follows:

Schedule 1	Not currently in use
Schedule 2	Pharmacy Medicine
Schedule 3	Pharmacist Only Medicine
Schedule 4	Prescription Only Medicine OR Prescription Animal Remedy
Schedule 5	Caution
Schedule 6	Poison
Schedule 7	Dangerous Poison
Schedule 8	Controlled Drug
Schedule 9	Prohibited Substance
Schedule 10 (formerly Appendix C)	Substances, other than those included in Schedule 9, of such danger to health as to warrant prohibition of sale, supply and use

Uniform Poisons Controls

The Poisons Standard also contains model provisions for the labelling, packaging, storage and possession of medicines and poisons that are adopted by states and territories. The storage, packaging and labelling provisions for Schedule 5-7 poisons were recently expanded as part of a national Uniform Poisons Control project, for adoption by all jurisdictions in the interest of national consistency. The ACT adopted these new provisions on 9 December 2015.

Scheduling policy and process

Scheduling provisions are set out under the *Therapeutic Goods Act 1989*, and by the Scheduling Policy Framework developed by the Australian Health Ministers Advisory Council (AHMAC). The Secretary of the Commonwealth Department of Health, or delegate, is the decision-maker for all scheduling proposals. Two separate Advisory Committees – the Advisory Committee on Chemicals Scheduling (ACCS) and Advisory Committee on Medicines Scheduling (ACMS) – may also advise the Secretary or delegate on scheduling proposals.

The ACMS and ACCS maintain a varied professional membership to ensure that they have appropriate knowledge and expertise to appropriately advise and make recommendations to the Secretary on the level of access required for medicines and chemicals.[1,2] The Therapeutic Goods Regulations 1990 (Cth) guarantees that all ACMS and ACCS members have expertise in a range of disciplines including practitioners, consumers, regulators and industry.[3]

All Australian states and territories have nominated representatives on the ACMS and ACCS to ensure that the views and impacts are also considered. The current memberships of the ACMS and ACCS is available from the Therapeutic Goods Administration website.[1,2] Where scheduling applications are received by the Secretary, a decision may be made with or without referring the matter to the ACCS or ACMS for advice. Where applications are referred to a scheduling committee for advice, the proposals undergo two phases of public consultation and decision making, including an interim decision and final decision by the Secretary or delegate.

All scheduling proposals are considered in accordance with section 52E of the *Therapeutic Goods Act 1989*. Matters that must be considered include the risks and benefits of a substance;the purposes for which a substance is used and extent of its use; the toxicity of a substance; he dosage, formulation, labelling, packaging and presentation of a substance; the potential for abuse or misuse of a substance; and any other matters relevant to the scheduling of a substance. The Scheduling Policy Framework also contains guidelines for classification of substances into each schedule.

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Controlled medicines and the ACT Medicines Advisory Committee

What are controlled medicines?

Controlled drugs, known as controlled medicines in the ACT, are substances that are listed under Schedule 8 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). They are potentially hazardous substances that are associated with an increased risk of abuse, misuse or dependence.[1] Because controlled medicines generally pose an increased public health risk, their manufacture, prescribing and supply are subject to strict regulatory controls under the *Medicines, Poisons and Therapeutic Goods Act 2008.* There are various restrictions on the prescribing of controlled medicines across Australia. In the ACT, with the exception of a few specifically defined circumstances,[2] a prescriber must have approval from the Chief Health Officer (CHO) to prescribe a controlled medicine for each patient. The requirement that prescribers seek CHO approval to prescribe a controlled medicine is explained in further detail in the Guidelines for Prescribers Prescribing Controlled Medicines.[2] The requirement to seek approval from the CHO to prescribe a controlled medicine is an administrative requirement that assists ACT Health to identify known public health risks associated with controlled medicines, such as doctor shopping, medicine misadventure and dependency issues. In most cases, applications for CHO approval to prescribe a controlled medicine (approval applications) are quickly approved as the proposed therapy is appropriate and represents a genuine clinical need. However, as part of the approval process, there are occasions when the CHO must make a risk-based decision to reject, or place limits on, a prescriber's approval to prescribe a controlled medicine in order to prevent patient harm or public health risk. Sometimes there can be conflicting or varying opinions about which treatment option is in the best interests of the patient. In these cases the CHO may refer the matter to the Medicines Advisory Committee (MAC) for advice. A prescriber may also request that the MAC review a CHO decision about an approval application or application to treat drug dependency and give an independent recommendation on the matter.

Photograph: Mix of medication. jk1991. FreeDigitalPhotos.net

The ACT Medicines Advisory Committee

The ACT MAC is an independent statutory committee under the *Medicines, Poisons and Therapeutic Goods Act 2008* that provides expert advice to the CHO about matters concerning controlled medicines. The MAC's primary functions include providing advice to the CHO about approval applications and applications for endorsement to treat drug dependency. The MAC provides a valuable community service by ensuring that CHO decisions are consistent with public health principles, community expectations and accepted clinical practices. To ensure the MAC can provide sound professional advice and services to the ACT community, MAC members must have demonstrated knowledge and/or experience in controlled medicines from either a medical, pharmaceutical or consumer perspective.

The MAC is comprised of up to seven members who are appointed by the Minister for Health for a term of up to three years. The MAC convenes approximately four times each year. In accordance with the Medicines, Poisons and Therapeutic Goods Regulation 2008, the MAC must maintain a varied membership that includes members with experience or practice in the areas of psychiatry; pain or addiction medicine; general practice; pharmacy; consumer representation; and a nominated member of the ACT Branch of the Australian Medical Association.[3]

The MAC can also develop guidelines for the CHO about how future approval applications should be processed (approval guidelines). The CHO must follow any approval guidelines when making decisions about approval applications.[3] As an approval guideline can indirectly determine a patient's ability to access treatment, all approval guidelines must carefully consider the interests of the patient and prescriber as well as any community impacts. For example, in early 2014 the MAC responded to increased community concern about accessing stimulant medicines (amphetamines) for the treatment of attention deficit hyperactivity disorder (ADHD). In consultation with the local medical community and public health consumer groups, the MAC subsequently developed approval guidelines for the prescribing of amphetamines for ADHD.[3] Anecdotal reports suggest that these measures have already helped multiple patients to better access treatment and manage their ADHD. The MAC will continue to consider emerging controlled medicines prescribing issues and develop further approval guidelines as appropriate.

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Controlled drug monitoring in the ACT

Michael Fitzsimons, Pharmaceutical Services Section, Population Health Division

Monitoring Controlled Drugs

Australia is experiencing a significant increase in the misuse of prescription opioid drugs. The National Pharmaceutical Drug Misuse: Framework for Action 2012-2015 outlined targeting drug misuse as one of its nine priorities. Another priority is the implementation of a nationally-based and consistent, real-time medication monitoring system for controlled drugs.

While awaiting the implementation of a national medication monitoring system, and to improve upon the monitoring of controlled drugs in the ACT, the Population Health Division of ACT Health has implemented its own medication monitoring system for controlled drug reporting. The ACT system is named the Drugs and Poisons Information System (DAPIS).

This system includes the ability:

- for ACT pharmacies to submit controlled drug dispensing information electronically (either in real-time or retrospectively); and
- to better alert the Chief Health Officer to patients and/or prescribers who, may be at risk of misuse, abuse and diversion of controlled drugs.

Introduction

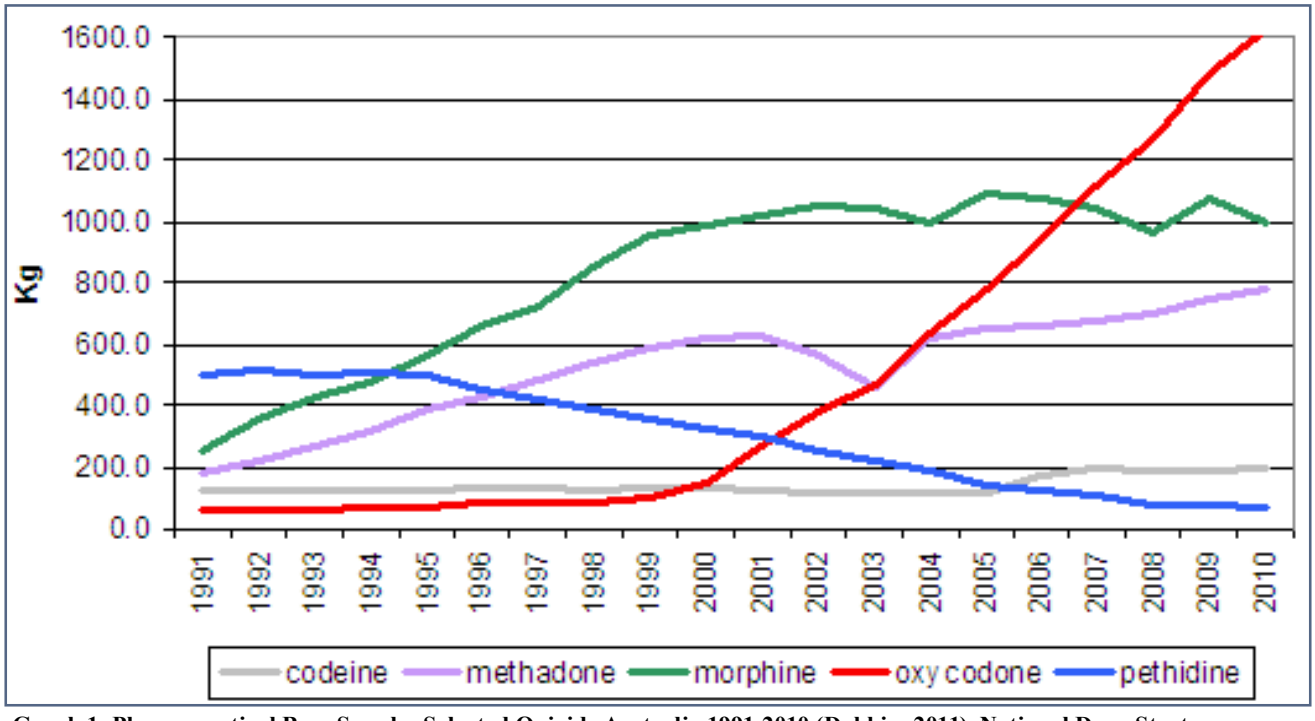
Australia, including the ACT. is experiencing a significant increase in the misuse of prescription opioid medicines.[1] This increase has followed similar trends in other countries, including the United States of America, Canada and New Zealand.

A significant number of people entering an alcohol and drug treatment program in Australia report unsanctioned use of prescription opioid medicines in the four weeks leading up to their program admission.[2] From 2002 to 2011, the Victorian telephone alcohol and drug counselling service, DirectLine, received more calls regarding prescription opioids than heroin.[3] The Sydney Medically Supervised Injecting Centre has also seen a shift to prescription opioid medicines as the drug most commonly injected by clients, exceeding heroin as the drug of choice.[4]

As part of the National Drug Strategy, the National Pharmaceutical Drug Misuse: Framework for Action 2012-2015[5] was released in early 2014. One of its nine priority areas was to target drug misuse through the implementation of a coordinated medication monitoring system. This system would include a nationally-based and jurisdictionally consistent real-time reporting system for all controlled drugs. Such a system would enable better regulation of controlled drugs such as prescription opioid medication. The ACT strongly supports the rollout of such a system.

The Australian Government Department of Health (DoH) has developed a national recording and reporting system for controlled medicines called the Electronic Recording and Reporting of Controlled Drugs (ERRCD). The development of this system was funded under the Fifth Community Pharmacy Agreement between the Pharmacy Guild of Australia and DoH. However, there is currently no agreement in place to rollout this system nationally.

Photograph: Pills. Amanda Mill. Public Health Image Library



Graph 1: Pharmaceutical Base Supply: Selected Opioids Australia 1991-2010 (Dobbin, 2011). National Drug Strategy.

Controlled drug monitoring in the ACT

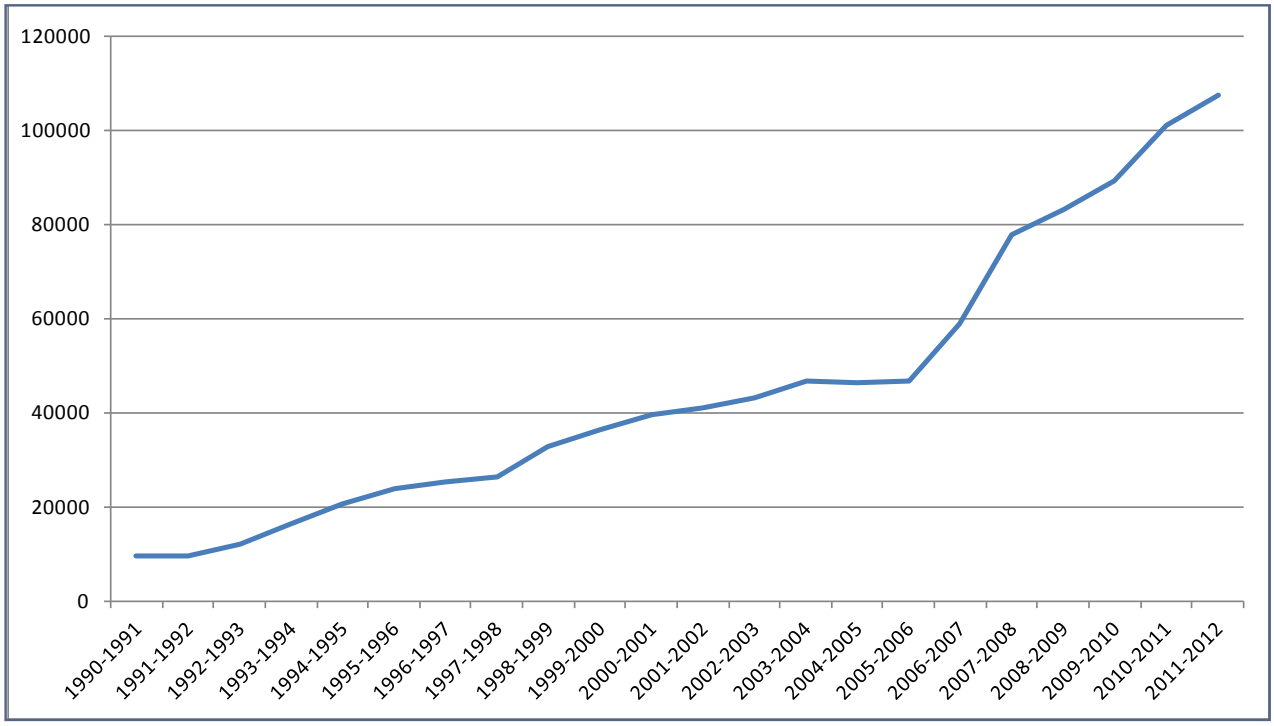
Controlled Drug Regulation in the ACT

Controlled drugs (also known as controlled medicines in the ACT) are substances listed in Schedule 8 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). These substances have a legitimate medical use but require restriction of manufacture, supply, distribution, possession and use due to the high public health risks associated with their misuse, abuse, diversion, physical and psychological dependence. Examples of controlled drugs are morphine and oxycodone used for severe pain, and dexamphetamine used for attention deficit hyperactivity disorder (ADHD).

The main benefits of the DAPIS include the ability:

- for ACT pharmacies to submit controlled drug dispensing information electronically (either in real-time or retrospectively); and
- to better alert the CHO to patients and/or prescribers who, based on the prescription data in DAPIS, may be at risk of misuse, abuse and diversion of controlled drugs.

DAPIS is enabling the CHO to more easily and quickly identify and mitigate public health risks associated with controlled drugs.



Graph 2: Number of controlled medicine prescriptions in the ACT - 1991- 2012. ACT Health

In the ACT, the *Medicines, Poisons and Therapeutic Goods Act 2008* (MPTG Act) and the Medicines, Poisons and Therapeutic Goods Regulation 2008 outline the regulatory restrictions on controlled drugs. The MPTG Act adopts the National Poisons Standard for the purposes of medicine and poison scheduling.

Provisions within the MPTG Act require all ACT pharmacies who supply controlled drugs on a prescription to provide information on the supply to the ACT Chief Health Officer (CHO). ACT pharmacies are required to submit controlled drug supply information to the CHO every seven days.

The CHO uses this information to:

- monitor public health risks associated with the misuse, abuse and diversion of controlled drugs; and
- assist in processing applications from prescribers requesting approval to prescribe a controlled drug(s).

Drugs and Poisons Information System

As an interim solution until the national ERRCD can be successfully introduced nationally, the Population Health Division is using a controlled drug reporting system called the Drugs and Poisons Information System (DAPIS) to monitor controlled drug prescriptions in the ACT.

DAPIS is modelled on a Tasmanian system and is compatible with the national ERRCD. As such, the ACT will be ready to participate in any national system when this is introduced.

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Novel psychoactive substances

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Novel psychoactive substances (NPSs) are a subset of designer drugs that are generally structural or functional analogues of existing controlled substances and mimic their psychoactive effects. Their foundations may be in historical pharmaceutical research or more recent clandestine manufacture. They form analogues that may be structurally related to a common psychoactive substance (e.g. cathinones) or have similar psychoactive effects to a known class of drug but are structurally unrelated (e.g. cannabimimetics).

There exists a vast number of NPSs and their manufacture, supply, distribution and use has increased significantly in the last few years. This increase has been facilitated by increases in ease of communication (e.g. the internet) and global distribution. Using cannabimimetics, as an example, some reasons that are given for this increased interest and choice to use them include: curiosity, legality, availability, physical effects, non-detection in drug testing and to reduce cannabis use.[1]

Legal history and status in the ACT

The ACT Criminal Code 2002[2] (Criminal Code), through its associated Criminal Code Regulation 2005 (the Regulation),[3] is the primary legislative instrument for control of illicit drugs in the ACT. Historically, substances have been controlled based on their exact chemical structure with, for example, 3,4-methylenedioxymethylamphetanine (MDMA/Ecstasy) and 3,4-methylenedioxyamphetamine (MDA/Eve) being individually listed in the Criminal Code. While related drug provisions within the Regulation allowed for coverage of substances with minor structural alterations, the coverage of NPSs were predominantly limited to simple amphetamine type NPSs. The majority of NPSs referred to as 'synthetic cannabimimetics' and the substituted cathinones, known as 'bath salts' generally escaped coverage, for example 4-Methymethcathinone (also known as 'Mephedrone' or 'Meow Meow') and alpha-Pyrrolidinovalerophenone (also known as 'a-PVP' or 'Flakka').

On 17 April 2014 amendments were made to the Regulation, which included the addition of approximately 30 new entries to the Prohibited Substance Schedule. Included in these additions were a number of individual synthetic cannabimimetics and several 'family' entries for common structures. The amendments also added a number of substituted cathinones including the 'NBOMe' series of drugs which have attracted significant negative media due to their implication in a number of Australian deaths.[4,5]

In combination with the unchanged related drug provisions, these amendments have allowed greater control of NPSs in the ACT. It has been noted however, that numerous substances which escape coverage under the amended regulations began to appear in the ACT almost immediately.

Analytical challenges

The analytical detection of such a wide variety of drug classes, and the sheer number of unique NPSs possible in seized substances and toxicological specimens poses a significant analytical challenge. Current legislative controls are based on chemical structure or, in some cases, pharmacological effect. In order for items to be captured within legislative controls, their identification must be accurate. Furthermore where pharmacological effect is utilised the chemical structure must then be evaluated to determine what, if any effects the substance may have. A recent review[6] collated investigations into approximately 80 cannabimimetics and 30 cathinones by colorimetric, immunochemical, and chromatographic methods. There are hundreds of other NPSs and new ones are regularly being discovered.

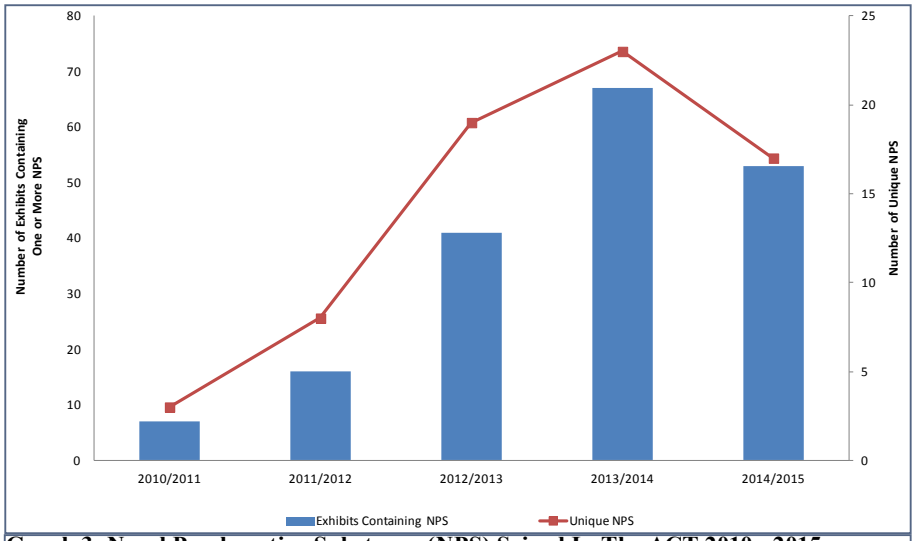
ACT recent findings

As shown in Graph 1, NPS seizures in the ACT have been increasing steadily since late 2011 with significant increases in 2012 and 2013. The increases have been in both the total number of seizures containing NPSs, and the number of unique NPS compounds being analytically detected. A range of examples from the major classes of NPSs have been detected in routine police drug seizures in the ACT. They have also been detected through the ACT Investigation of Novel Substances (ACTINOS) program, which investigates drug exhibits associated with hospital admissions. These include synthetic cannabimimetics, novel piperazines and novel amphetamine type substances, including various substituted cathinones and the NBOMe series of drugs.

Summary

Novel psychoactive substances, which are structural or functional analogues of and mimic the effects of existing controlled substances, have recently and rapidly emerged in society. These NPSs continue to cause significant health problems and complex legal and analytical challenges.

NBOMe series of drugs are 'derivatives of N-(2-methoxybenzyl)-2,5-dimethoxy-phenethylamine'. ie. N-(2-methoxybenzyl)-2,5-dimethoxy-4-chlorophenethylamine = '25C-NBOMe' and N-(2-methoxybenzyl)-2,5-dimethoxy-4-Bromophenethylamine ='25B-NBOMe'



Graph 3: Novel Psychoactive Substance (NPS) Seized In The ACT 2010 - 2015 (Number of Exhibits Containing an NPS & Number of Unique NPS)

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Medicinal Cannabis: Striking a balance between compassion and public health risk

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The Cannabis plant, also known as 'marijuana', is native to Asia and has been used for recreational, ceremonial and medicinal purposes by many societies since ancient times. Although considered an illicit drug since the early 20th century, and controlled by international conventions which restrict its growing and trade, interest in the medicinal use of Cannabis has continued. Glaucoma, cancer-related pain, chemotherapy-related nausea, chronic pain, wasting associated with Acquired Immunodeficiency Syndrome (AIDS) and epilepsy are among the conditions for which Cannabis has been proposed as a potential treatment.[1] This has led to the development by the pharmaceutical industry of synthetic cannabinoids for nausea and limited pain indications. However, these have had limited success in the market and have not met the need for botanical Cannabis asserted by advocates of the medicinal use of Cannabis.

Approaches to the Regulation of Medicinal Cannabis

In many countries there has been a loosening of the laws restricting the possession and cultivation of Cannabis for medicinal use, either in isolation or in tandem with increased provision for recreational use of cannabis.[2] There are significant differences in the approaches taken in jurisdictions seeking to facilitate access to Cannabis for medicinal purposes, often determined by local legal constraints and the desire to limit potential public health harms from increased use of Cannabis. Australia does not yet have a scheme for allowing access to medicinal Cannabis, but the issue has attracted political, media and advocacy interest in all states and territories over the past year. The focus on Cannabis as a potential therapy, coupled with the need to address potential public health risks associated with increasing availability, have meant that health departments have been central to providing advice on whether and how best to provide for medicinal Cannabis in Australia.

Australia has a well developed medicines regulatory system in which the Therapeutic Goods Administration (TGA) assesses the quality, safety and efficacy of medicines prior to them being marketed. Unfortunately, botanical Cannabis poses a number of challenges for this system.

Firstly, the Cannabis plant produces a large range of active ingredients collectively known as 'cannibinoids'. These include Δ9-tetrahydrocannabinol (THC), which is associated with the psychoactive effects of the plant when ingested or smoked, and Cannabidiol (CBD), which may moderate the effect of THC and has shown some potential as an antiepileptic and antispasmodic agent.[1] The effect of Cannabis depends on the mix of cannabinoids in a given plant, which can vary greatly between strains and growing conditions,[1] and this means it is difficult to standardise a product to the extent necessary to obtain regulatory approval.

Secondly, Cannabis is a natural product with no corporate 'sponsor' with a commercial interest in performing the large medical trials necessary to secure regulatory approval. Despite a wealth of observational and anecdotal data, there have been very few high quality clinical trials conducted to determine the effectiveness of Cannabis,[3-5] and these types of trials require significant investment.

Finally, the propagation and possession of Cannabis is illegal in most jurisdictions which would complicate the sale of a botanical medicinal Cannabis product. The manufacture of synthetic cannabinoids in a standardised pharmaceutical dose form, such as Nabiximols (Sativex®), represents the application of the standard drug development model to Cannabis. While there is evidence for the efficacy of these pharmaceutical products in alleviating the symptoms associated with some conditions,[6] this approach does not inform the potential medicinal use of botanical Cannabis.

Schemes in Other Jurisdictions

The schemes which have been implemented to allow medicinal use of botanical Cannabis have dealt with not having a 'traditionally' regulated pharmaceutical in several ways. One group of schemes has provided purely legal relief from criminal prosecution stemming from the possession and growing of cannabis where a person has a recommendation from a doctor.[2] A second group of schemes is more permissive of growing medicinal Cannabis by collectives or clubs which people can access with a prescription from their doctor.[2] The third approach is to have a sole supplier of a standardised, regulated product through a prescription process.[2] In each of these models, the issue of the clinical safety and efficacy of Cannabis is left to the assessment of doctors prescribing or recommending the product. The issue of the quality of the Cannabis supplied is either left in the hands of illicit suppliers, third party groups or a Government-sponsored provider. The risks associated with medicinal Cannabis include the potential for toxicity in people ingesting it, as well as its interaction with other medicines, such as anticonvulsants. These approaches have also attempted to balance the potential benefits of medicinal Cannabis to ill people with the risks to public health, such as diversion of product to recreational use, inappropriate clinical use and hazardous driving. Each has only been partially successful in finding this balance.

Legal relief for people accessing the illicit Cannabis market under authority from their doctor has been implemented in several jurisdictions, such as Rhode Island in the USA.[7] This has been seen as a politically cautious step because it involves minimal change to legislation and, in particular, does not require legalisation of the cultivation and sale of Cannabis. The problem with this is that patients have the expectation that, when a doctor recommends Cannabis, it is available. Many patients are not able to easily obtain illicit product and this has been a major source of consumer dissatisfaction with the Rhode Island scheme.[7] It also requires patients to have contact with criminal enterprise and this can lead to vulnerable people being put at risk of violence or being exploited.[7] Since the supply of Cannabis in this kind of scheme is completely unregulated, the quality of Cannabis people obtain can vary significantly over time. This is particularly relevant given the effect different combinations of cannabinoids can have on the therapeutic effect of the product.[1]

Photograph: Cannabis leaf. Paul, FreeDigitalPhotos.net

Medicinal Cannabis: Striking a balance between compassion and public health risk

The experience in Rhode Island, and in other jurisdictions in the USA which have allowed medicinal Cannabis on medical authority, is that it ultimately requires legalisation of cultivation to meet patient demand for access. Colorado (which has now also legalised recreational use of Cannabis), California and Canada have all implemented schemes which allow patients, or a third party appointed by them, to cultivate cannabis for medicinal use once it is prescribed.[2] Where this has been done it has improved access to medicinal Cannabis and, arguably, led to the development of knowledge and capacity among growers of how to produce stable varieties for different medical conditions. One problem with this kind of system is that the regulatory 'gatekeeper' role is entirely delegated to doctors who prescribe medicinal Cannabis, and there is evidence that this can fail. In Colorado, the majority of medicinal Cannabis scripts were written by a small number of clinicians and there was a high proportion of young male patients inconsistent with the indications for chronic and cancer-related pain.[8] Individual authorities to cultivate Cannabis can be grouped into significant commercial enterprises nominally producing for hundreds of patients, but auditing the veracity of these individual's approvals is prohibitively resource intensive for law enforcement. It is likely that a component of Cannabis grown by third parties is diverted into recreational use either by inappropriate prescribing or failure to control the quantity being grown.

The Netherlands is a well known and discussed case of a country in which the supply of medicinal Cannabis occurs in a highly developed regulatory framework. Contrary to popular opinion, recreational use of Cannabis is not legal in the Netherlands but it does maintain a policy of discretionary legal enforcement for possession.[9] Medicinal Cannabis is cultivated and manufactured by providers on behalf of the Government of the Netherlands under strict regulation in line with stringent quality control standards. This is dispensed through pharmacies, paralleling the standard distribution of other medicines. There is evidence that the medicinal use of Cannabis is lower in the Netherlands than in schemes based on grower's collectives, and the patient's age is more consistent with the expected medical indications.[10] This is allowed under international conventions because the Government is the sole purchaser of the entire medicinal cannabis crop and can account for its distribution. A significant advantage of this model is the stable quality of the Cannabis, which allows doctors to be educated about its appropriate use, and patients to have consistency in its therapeutic effect. This is very similar to the arrangements the Victorian Government announced on 6 October 2015 following a review by the Victorian Law Reform Commission into cannabis supply.[11]

Photograph: Industrial Cultivation. Public Domain

Conclusion

There is broad advocacy to allow the use of cannabis for medicinal purposes in Australia and Governments have responded in a number of ways. The medical profession is aware than many people with chronic or terminal illness take cannabis and is not necessarily averse to its inclusion in the pharmacopaea, a move which would be 'back to the future' given its long historical use. In order for Cannabis to be incorporated into medical practice, however, it is essential that a consistent, quality controlled product is available. The potential for diversion of medicinal cannabis into recreational use leading to de-facto legalisation, or for poor prescribing to harm patients has to be considered in any scheme to provide medicinal Cannabis. These are common concerns in pharmaceutical regulation generally, but the unique characteristics of botanical Cannabis have meant that Governments have been asked to take over the assessment of these issues from drug regulators. Australia can learn a lot from the different approaches which have been taken to the regulation of medicinal Cannabis overseas in an attempt to balance clinical and public interest, and it seems that movement is occurring towards a highly regulated supply which could be of significant benefit.

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Kava: understanding the concerns of the ACT Pacific Islander community

Kava (*Piper methysticum*) is a plant native to the Pacific Islands that has been used as a ceremonial and relaxing drink by people of that region for centuries. It holds a deep cultural importance in the life of Pacific Islander people, including those living within the ACT. The traditional kava drink is prepared from water extracts of the raw kava root. It is traditionally served from a wooden bowl (or 'kumete') and is consumed on special occasions (such as births, deaths or marriages), at social gatherings to strengthen kinship ties, or as a mark of respect to welcome elders or chiefs at official gatherings. Kava has also been used in Western medicine for the treatment of anxiety, and is available in some medicinal products in tablet, capsule or tea bag form.

Local and international health concerns with kava

The health risks of traditional kava use are generally regarded to be low. When consumed, kava can have a sedative or anaesthetic-like effect. Kava can cause nausea, sleepiness and reduced muscle control. Kava gained international attention in the early 2000s following widespread reports of liver toxicity. The World Health Organization commissioned a report on this phenomenon in 2007[1], and concluded that the risk of hepatotoxicity was primarily with the medicinal formulations (ethanolic extracts). This led to tighter controls on medicinal kava preparations worldwide, including in Australia, where medicinal kava products were listed as a Schedule 4 (prescription only) medicine. In Australia, tighter controls were later introduced in response to alarming reports of kava abuse and misuse, particularly in remote Northern Territory Aboriginal communities. In 2008, the Schedule 4 listing for kava was extended to include traditional forms of kava due to these public health and social concerns.

Kava laws in the ACT and Australia

Kava is listed as a Schedule 4 medicine under Commonwealth law. This listing is adopted locally in the ACT under the *Medicines, Poisons and Therapeutic Goods Act 2008*, with corresponding restrictions that it may only be supplied on prescription. Some states and territories have introduced tighter controls on its supply, such as in the Northern Territory and Western Australia where it is prohibited. Importation of kava in Australia is also prohibited without a permit under the Customs (Prohibited Imports) Regulations 1956. An exemption applies to incoming passengers to Australia, who can carry up to 2kg kava on their person.

ACT Health working with the ACT Pacific Islander community

The prescription only restrictions on kava have caused much concern within the ACT Pacific Islander community, as they effectively prohibit traditional kava use. These concerns were highlighted to the ACT Government in 2011 as a restriction to Pacific Islander culture and religious activities.[2] ACT Health consequently submitted a rescheduling application to the Therapeutic Goods Administration (TGA) in 2011 to exempt traditional forms of kava from the schedule 4 listing. This application was submitted to the TGA in recognition of the low health risks of traditional kava use and the deep cultural importance of kava in Pacific Islander life. This submission was not successful, which led to ACT Health working closely with the Office of Multicultural Affairs and relevant community groups to put a temporary exemption in place to allow for the traditional use of kava the 2012 National Multicultural Festival.[2]

Following this, in 2013 the ACT Government introduced an amendment to the Medicines, Poisons and Therapeutic Goods Regulation 2008, to permanently exempt traditional forms of kava from the prescription only requirements when served at certain public events as declared by the Minister for Health. The National Multicultural Festival was the first public event to be declared as exempt, however a small number of public events run by the ACT Pacific Islander community have also been declared. Conditions have been applied to exemption declarations in order to ensure the appropriate use of kava for cultural purposes and to minimise any potential risks to public health. This includes restrictions on the advertising and signage of kava at public events. Restrictions have also been applied to serve kava from single use cups at events, so as to minimise risk of contamination arising from use of shared traditional wooden cups. This issue has required ACT Health to step beyond its usual health role and engage closely with a minority ethnic group within the community to better understand their cultural practices and concerns. Allowing for the cultural use of kava at approved events is an example of how ACT Health undertakes a pragmatic, risk-based approach in the management and promotion of public health.[3] ACT Health continues to work with the ACT Pacific Islander community and Office of Multicultural Affairs to assist the community's understanding of local kava restrictions and address their concerns.

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Photograph: Bag of Kava. Victoria Burchfield, MLIS

Public health boost from pharmacist-delivered vaccinations

Pharmaceutical Society of Australia, ACT Branch

Pharmacists have a significant role to play in addressing public health priorities including immunisation, especially as recently there have been increases observed in hospitalisations due to vaccine-preventable conditions in Australia.[1]

In the United States, it is commonplace for consumers to receive seasonal influenza immunisations from pharmacists.[2] In New Zealand, suitably credentialed pharmacists may also provide influenza vaccinations.[3,4]

In Australia, up until the Pharmacy Board of Australia's (PBA) announcement in 2013 that in its opinion, administering vaccines was within the scope of practice of an appropriately trained and registered pharmacist,[5] there was a reluctance to devolve any primary care responsibility away from general practitioners.

The PBA announcement was a watershed moment, with individual jurisdictions taking the opportunity to better utilise pharmacists and their skills in administering vaccinations.[6] Increased vaccination rates are known to improve herd immunity, improve the allocation of health funding and reduce the burden of disease and stresses on local health systems.[7,8] Since the PBA announcement, significant progress has been made towards pharmacists providing and administering vaccinations.

Pharmacists are among the most trusted and accessible professionals in Australia.[9] Their role relates not only to medicines' use and management but also to providing advice on non-drug management where appropriate, providing support and information, and working across the whole spectrum of health from maintenance of good health to management of ill health.[10]

Following the PBA's announcement, the Queensland government authorised a number of community pharmacies to provide immunisation services to walk-in patients without a prescription under the Queensland Pharmacist Immunisation Pilot (QPIP). The pilot was launched in January 2014 and aimed to determine the potential public health benefits of extending consumer access to influenza vaccination through community pharmacists. The QPIP program also included several requirements to ensure the safe operation of influenza vaccination services by community pharmacists.[7]

These requirements included:

- demonstrated competency to administer vaccines;
- additional training and education about immunisation;
- ability to appropriately manage immediate adverse events;
- minimum requirements for appropriate clinical infrastructure and procedures; and
- minimum reporting requirements.

As a result of the QPIP program, over 10,000 vaccinations were administered by 80 participating community pharmacies without any significant adverse events recorded.[7] Among the QPIP outcomes, the pilot demonstrated that pharmacists can boost public health outcomes through providing immunisation services. For this reason, the QPIP program was expanded on 1 September 2014 to allow pharmacists to administer the whooping cough and measles vaccines to patients without a prescription.[11]

Pharmacists are competent health care providers, and are ready to assist the ACT Government to deliver a greater range of professional services to the ACT community to reduce the burden of disease and general ill health.

The Pharmaceutical Society of Australia (PSA) strongly supports the implementation of a pharmacist vaccination program in the ACT that would allow credentialed pharmacists to provide immunisation services in a variety of practice settings. Pharmacist-delivered vaccinations may also deliver further business and professional development opportunity for local pharmacists as well as increase consumer choice and access to immunisation services.

Photograph: Immunisation. David Castillo Dominici - Freedigitalphotos.net

Public health boost from pharmacist-delivered vaccinations

While the ACT enjoys high rates of vaccination from a whole-of-territory perspective, there are areas of Canberra that have rates of immunisation lower than the national average.[12] Any opportunity to maximise population health benefit, by utilising an existing workforce, should be dutifully considered and assessed.

ACT Health recently finalised a consultation process on the proposed introduction of a pharmacist vaccination program for the 2016 flu season. The ACT Government is currently reviewing all responses to the consultation and has not yet reached a final decision

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Regulation of the pharmacy profession in the ACT

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Pharmacies and pharmacists play a vital role in the health care system by ensuring that medicines are used wisely and that consumers are provided with appropriate advice about their health care needs. However, the profession is required to be regulated to ensure the safe and effective use of medicines. Medicines and the profession are regulated through various means such as state and territory legislative frameworks, the Pharmaceutical Benefits Scheme, the regulation of the Therapeutic Goods Administration, the Quality Care Pharmacy Program, etc. This article describes the legislative frameworks in the ACT and their role in protecting public health and safety.

The pharmacy profession in Australia has been regulated since the nineteenth century.[1] Effective regulation of the profession is important to protect the health, safety and wellbeing of people using its services. Each jurisdiction in Australia has a local government authority or an independent Pharmacy Administrative Authority that is responsible for conducting a range of regulatory activities in relation to the profession. These regulatory activities include approval of pharmacy ownership, registration of pharmacy business premises, and monitoring and enforcement of state and territory medicines and poisons legislation. The Health Protection Service (HPS) within the ACT Government Health Directorate regulates and enforces local legislation around pharmaceuticals and the pharmacy profession.

Photograph: 19th Century pharmacy. Wellcome Trust. Public Domain

National pharmacist registration

Pharmacists are required to be registered with the Pharmacy Board of Australia (PBA) and meet the Board's registration standards in order to practice in Australia.[2] Pharmacist registration with the PBA is recognised in all states and territories in Australia under the National Registration and Accreditation Scheme (NRAS). The NRAS for health professionals was implemented in July 2010 to facilitate health professional workforce mobility and ensure the continuous development of a flexible, responsive and sustainable workforce. This resulted in the formation of 14 National Boards, including the PBA.[3] Prior to the establishment of the NRAS, each state and territory maintained local health boards to administer all functions relating to the profession, including individual pharmacist registration and pharmacy ownership. Following the introduction of the NRAS, these local health boards, including the PBA of the ACT, ceased to operate.

The Australian Health Practitioner Regulation Agency (AHPRA) provides administrative support to the National Boards. The PBA and the AHPRA work together on pharmacist registrations and to determine the necessary requirements for registration. They investigate complaints or concerns regarding the performance or conduct of pharmacists, and take appropriate actions when required.[4] The PBA also develops standards, codes and guidelines for pharmacists and the profession.[5] These may be accessed via the Pharmacy Board website.

The ACT recognises the registration standards, guidelines, codes and policies issued by the Pharmacy Board under the Health Practitioner Regulation National Law (ACT). This framework and the professional standards set by the PBA help to protect the public by ensuring that only suitably qualified and trained persons are registered to practice. The PBA also provides standards for continuing professional development for pharmacists.

Pharmacy Ownership and Premises

ACT Health regulates ownership of community pharmacies and pharmacy premises by utilising the licensing provisions in the *Public Health Act 1997*. The operation of a community pharmacy is declared as a licensable public health risk activity under the Public Health Act; hence community pharmacies must be licensed. The Public Health Act also outlines who may own and operate a pharmacy business. In addition, community pharmacy licence holders need to comply with the Public Health (Community Pharmacy) Code of Practice 2012 (No 1), which outlines general requirements for pharmacy owners and pharmacy premises.

Prior to the introduction of the NRAS, the Pharmacy Board of ACT performed these regulatory activities in accordance with the Health Professionals Act 2004. Certain provisions of the Health Professionals Act were repealed, and comparable provisions were incorporated into the *Health Practitioner Regulation National Law (ACT) Act 2010* (National Law). However regulation of pharmacy ownership and premises fell outside the scope of the NRAS and remains the responsibility of the states and territories.

In accordance with sections 66v and 66w of the Public Health Act, only a registered pharmacist or a group of pharmacists may own a pharmacy in the ACT. A pharmacy must also be under the direct control of a pharmacist. This ownership arrangement provides quality use of medicines and value-added primary health care services in pharmacies. Primary health care services include medication management, wound care management, diabetes management, distribution of public health education materials, etc. These various health care services in pharmacies show the willingness of pharmacy owners to give priority to important health care activities over the profitability or commercial viability of the activity. It also ensures responsibility and accountability for pharmacy services provided by pharmacist owners.[6]

These frameworks of governing pharmacy ownership and premises ensure adequate pharmacy ownership restrictions, high standards of pharmacy operation, and protect the public from unsafe operation of pharmacy businesses. Community Pharmacy Licence application forms may be accessed via the ACT Health website.

Photograph: Modern Pharmacy. AmerisPharma. Public Domain

Regulation of the pharmacy profession in the ACT

Medicines authorisations

In the ACT, some health-related occupations, including pharmacists, are authorised to deal with medicines in a particular manner under the *Medicines, Poisons and Therapeutic Goods Act 2008* (MPTG Act). Pharmacists are authorised to purchase, obtain, possess, supply, dispense and administer medicines to the extent necessary to practice pharmacy and within the scope of employment. The Medicines, Poisons and Therapeutic Goods Regulation 2008 contains more substantive details, specific requirements and conditions for a range of activities, such as labelling, recording, storage and handling of medicines. Pharmacists are required to deal with medicines in accordance with the MPTG Act and subordinate Regulation.

The states and territories are responsible for regulating and enforcing health professionals' authorisations to deal with medicines. This framework promotes and protects public health and safety by requiring that health professionals meet specific requirements when dealing with medicines.

Photograph: Community Pharmacist. Public Domain

Compliance and enforcement

In order to effectively regulate the pharmacy profession, the HPS also conducts monitoring activities and undertakes investigations and enforcement action if required. Routine inspections of pharmacy businesses are performed to determine their compliance in accordance with the Public Health Act and the MPTG Act. The HPS works with pharmacists and pharmacies to assist with education and compliance with the legislation. Serious breaches are investigated and enforcement action is undertaken if required. A matter may also be referred to the PBA for its own records and to consider further investigation of professional practice issues against a pharmacist.

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The future opportunities for community pharmacy

Margaret Beerworth, Branch Director, The Pharmacy Guild of Australia, ACT Branch

There are over 5,510 community pharmacies in Australia. There are currently 74 community pharmacies operating in the ACT. Community pharmacies serve the local community through the provision of medicines, advice and, increasingly through the provision of primary health care services.

In the ACT, pharmacies are distributed geographically with a view to being widely accessible. Some pharmacies offer extended trading hours, and in some cases operate seven days a week.

Pharmacies are often the first port of call for patients seeking medication, or advice about minor ailments. This article outlines current use of, and future opportunities for, community pharmacies as a means of providing primary health care.

Pharmacies in Australia offer a highly skilled network of primary healthcare professionals providing healthcare advice and services. The Pharmacy Guild of Australia (Pharmacy Guild) is a national pharmacy organisation that represents the majority of Australia's 5,450 pharmacies. The Pharmacy Guild believes there is an ongoing need for primary health care reform in Australia to ensure that all arms of the health system work in a coordinated way that maximises the system's efficacy and efficiency.

The Pharmacy Guild is of the view that public health outcomes can be improved through pharmacist involvement in health education, preventative health and early disease identification, in collaboration with other health professionals. This may assist to lessen the current burden on GP and hospital resources. Effective referral systems between allied health and medical professionals, in addition to extended professional scope of practice pathways, could also provide public health benefits by expanding the availability and skills base of Australia's health workforce.

Below are several examples of ways in which community pharmacists may better contribute to improved public health outcomes.

An opportunity to address medicines adherence issues

Adverse medicine events account for an estimated 190,000 hospital admissions per year.[1] Costs to the health system are estimated at $660 million annually and 50 percent of these adverse events are avoidable.[1] Furthermore, medication adherence rates in Australia are low, averaging only 50-65 percent.[2] Poor adherence to medications can lead to adverse health outcomes, hospitalisations, and increased health care costs.

A 2012 study by the IMS Institute for Healthcare Informatics identified six main levers that can exacerbate overall health system costs and jeopardise health outcomes. These are: non-adherence to medicines (i.e. usage not in accordance with medical direction); untimely medicines use (i.e. patients not obtaining medicines at the appropriate time); antibiotic misuse/overuse; medication errors; suboptimal use of generic medicines; and mismanaged polypharmacy (i.e. simultaneous use of multiple medicines).[3] This study estimated that there are AUD $6 billion worth of avoidable costs in Australia across these six areas (or 7.7 percent total health expenditure), with non-adherence to medicines being the greatest contributor to this figure.[3]

There is evidence that a relatively modest investment in the quality use of medicines would help to reduce unnecessary hospital and premature aged care facility admissions.[4] Due to the expertise in medicines that trained pharmacists have, there is an opportunity for pharmacists to collaborate with other healthcare providers to make a real impact on this issue.

An opportunity in preventative health and education

An enhanced role for pharmacists in preventative health care and education may provide some patients with improved health outcomes. There is a growing opportunity for pharmacists to better assist patients through health and wellness assessments, as well as in the promotion and management of healthy lifestyle choices, such as smoking cessation. Pharmacy health and wellness assessments typically examine a patient's blood pressure, cholesterol, blood glucose, body measurements and lung function. For example, 52 community pharmacies in the ACT are currently participating in the Pharmacy Guild ACT Branch's Smoking Cessation Counselling project. This project is funded by the ACT Health Promotion Grants Program. The project allows pharmacists and pharmacy assistants to attend training in smoking cessation counselling and nicotine replacement therapy, respectively. For more information see article on page 23.

An opportunity for pharmacist-led vaccination

Most jurisdictions in Australia have now legislated for pharmacists to administer vaccinations without a prescription in defined circumstances. All states and territories except the ACT, Victoria and Tasmania now allow for pharmacists to administer the influenza vaccine to walk-in patients without a prescription. Pharmacist-led vaccination pilot programs in Queensland and the Northern Territory also authorise some pharmacists administer the pertussis (whooping cough) and measles vaccines. The ACT Government is currently considering a proposal that would authorise ACT pharmacists to offer immunisation services. For more information see article on page 17.

An opportunity for pharmacists to treat minor ailments

Many people visit their General Practitioner (GP) as the first line of treatment for illness. In some situations, patients may benefit from visiting a community pharmacy for non-emergency healthcare advice and treatment of some minor ailments. For example, a pharmacist may assist patients with minor medical conditions, such as uncomplicated fungal infection or hay fever. When minor, these ailments can be appropriately managed in the community pharmacy setting. Alternatively, if a pharmacist identifies a more serious condition, such as hypertension, they are well placed to refer the patient to an appropriate medical professional.

Opportunity for care transition

On admission to hospital, up to 50 percent of patients have an incomplete current medications list, resulting in medicines not being provided during the hospital stay.[5] Additionally, 12 percent of patient discharge summaries have an error in the discharge prescription, 73 percent of GPs do not directly receive discharge summary information, and 9 percent of patients are discharged from hospital with insufficient supplies of medicine.[5]

There is need for a coordinated multidisciplinary approach, involving hospital and community pharmacists, GPs and the patient's family or friends, to ensure a full medicines history is provided on admission to hospital. Both hospital and community pharmacists can play a key role in helping patient's to understand their medicine management needs when transitioning to and from hospital care. Less than 2 percent of people leaving hospital receive a discharge plan, case conference or medication review within the first month

The future opportunities for community pharmacy

after discharge.[6] Further, data suggests that 30 days post-hospital discharge, 71 percent of patients visit their GP within a median time of 12 days, while 86 percent of patients visit their pharmacy within a median time of 6 days.[6] These data may support an expanded role for pharmacists to assist patients regarding their medication needs post-discharge.

Opportunity for after-hours care

A pharmacist must be on duty whenever a community pharmacy is in operation. The extended trading hours of many community pharmacies (e.g. evenings, weekends and public holidays) makes them one of the most accessible healthcare service providers. Given that 80 percent of GP visits result in a patient prescription,[7] it would be counterintuitive to enhance community access to GPs after-hours without addressing the flow-on need for increased access to the dispensing of medicines.

In summary, community pharmacy in Australia is an essential, cost-effective and highly accessible healthcare service. Pharmacists, in collaboration with other health professionals, have the capacity and skills to deliver a broader set of healthcare services to the Australian community.

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Community Pharmacy Service Charter

This Charter provides information on the rights of consumers and responsibilities of pharmacists, and the level of service consumers can expect to receive when visiting a community pharmacy. It allows patients, consumers, families, carers and community pharmacies to share an understanding of the rights of people receiving health care.

Guiding Principles

These three principles, adopted from the **Australian Charter of Healthcare Rights**, describe how this Charter applies in community pharmacy.

1. Everyone has the right to be able to access health care and this right is essential for the Charter to be meaningful.
2. The Australian Government commits to international agreements about human rights which recognise everyone's right to have the highest possible standard of physical and mental health.
3. Australia is a society made up of people with different cultures and ways of life, and the Charter acknowledges and respects these differences.

As part of this pharmacy's commitment to providing quality services to the community, a **Customer Service Statement** for this pharmacy is also on display.

What can I expect from a community pharmacy?

My rights	This pharmacy's commitment to you
Access I have a right to health care.	We will provide medicines and pharmacy related services and products to address your healthcare needs.
Safety I have a right to receive safe and high quality care.	We will provide safe and effective medicines and high quality pharmacy related services, with professional care, skill and competence.
Respect I have a right to be shown respect, dignity and consideration.	We will respect you and your culture, beliefs, values and personal characteristics and those of your carers and advocates when delivering services.
Communication I have a right to be informed about services, treatment, options and costs in a clear and open way.	We will provide you open, timely and appropriate communication about your health, medicines and related services in a way you can understand.
Participation I have a right to be included in decisions and choices about my care.	We will include you in making decisions and choices about your health, medicines and related services and products.
Privacy I have a right to privacy and confidentiality of my personal information.	Unless you otherwise consent, we will maintain your personal privacy and assure proper handling of your personal health and other information. We will provide a private area to discuss your needs.
Comment I have a right to comment on my care and to have my concerns addressed.	We will promptly address your comments or concerns about medicines or other services offered.

Disclaimer – community pharmacy can only provide healthcare within the legal scope of pharmacy practice.

If you want more information about how this Charter works, ask us here at this pharmacy or visit: www.health.gov.au/pharmacy

If you have concerns or comments about the quality of service you have received, please talk to the pharmacy staff in the first instance or you may contact the Australian Health Practitioner Regulation Agency (www.ahpra.gov.au) or your state or territory health complaints commission.

Australian Government
Department of Health and Ageing

The Pharmacy Guild of Australia

This Project is funded by the Australian Government Department of Health and Ageing as part of the Fifth Community Pharmacy Agreement.

The ACT Community Pharmacy Smoking Cessation Program

Rosemary Urquhart, ACT Health Promotion Grants Program, Population Health Division &
Margaret Beerworth, Branch Director, The Pharmacy Guild of Australia – ACT Branch

Despite gains in recent decades, tobacco-related harm remains a significant contributor to burden of disease in Australia and the ACT. There is a strong rationale for conducting activities to reduce tobacco-related harm within a pharmacy setting. Not only do pharmacies dispense products related to smoking cessation, pharmacists are also seen as reliable and credible sources of health information and advice.

The Community Pharmacy Smoking Cessation Program, funded through the ACT Health Promotion Grants Program, seeks to leverage these factors by providing pharmacy staff with the appropriate skill set to be able to improve health outcomes. The Program features a significant training component to provide pharmacy staff with counselling skills to conduct brief interventions. The use of on-site technologies, such as Smokerlyser® devices to measure both lung function and carbon monoxide levels in customers, can also act as a significant agent for change.

The initial findings from the Program are positive and detailed evaluation work is underway.

Introduction

The ACT compares well to other jurisdictions in having relatively low rates of smoking amongst adults. In 2011-12, 15 percent of ACT residents aged 18 years and over reported being current smokers compared with 18.1 percent of adult Australians.[1] ACT smoking rates are also consistently trending downwards. However tobacco-related harm remains a significant cause of burden of disease in Australia.[2]

The ACT Branch of the Pharmacy Guild of Australia (Pharmacy Guild) secured a two-year grant through the ACT Health Promotion Grants Program to develop and implement a pharmacy-led smoking cessation initiative in the community pharmacy setting. The Smoking Cessation Counselling Program (the Program) commenced in July 2014. The goal of the Program is to increase the uptake of smoking cessation programs and ultimately to increase successful long term quitting. This type of project has been successfully implemented in other countries and is based on the Smoke Free Ontario Study 2011.[3]

Rationale: why community pharmacy as a setting

Community pharmacy is one of the most accessible health services. The ACT has 74 local pharmacies and the Phamacy Guild estimates that there were approximately 7 million visits to ACT pharmacies in 2013-14. Pharmacies that supply smoking cessation products are well placed to provide trusted advice and support.[4,5] Evidence suggests that trained pharmacists can deliver cessation interventions and help smokers quit.[6,7]

Photograph: Breaking the habit. Gameanna. FreeDigitalPhoto.net

ACT pharmacists already provide advice to patients on the risks of smoking during dispensing or front-of-shop interactions. Brief one-to-one counselling by health care providers for three to eight sessions, of at least three minutes, has been shown to increase the chances of prolonged abstinence.[8] Treatment delivered by a variety of clinician types has also been shown to increase abstinence rates,[8] therefore having pharmacists trained in smoking cessation approaches could increase the number of people who decide to quit smoking. ACT pharmacists provided feedback that they would support the Program.

Methods

As part of the Program, ACT pharmacists and pharmacy assistants were invited to attend smoking cessation counselling training with a view to then being able to offer a smoking cessation service to their customers in a number of formats, including short interventions, sit-down consultations, and in-pharmacy or telephone follow-up.

Additionally, seven pharmacies across the ACT were selected to deliver a more in-depth service, using PiKo-6® and Smokerlyser® devices to measure both lung function and carbon monoxide levels in their customers. The seven pharmacies were selected based on their proximity to groups with higher smoking rates than the general population.

The Program is being extensively evaluated. Data is being collected from all participating pharmacies and includes de-identified clinical data of interventions, risk assessments and the number of smokers engaged in counselling programs and their outcomes. Pharmacies with PiKo-6® and Smokerlyser® devices are also recording the results of lung function tests.

Photograph: Smokerlyser. CoVita.net

Results

To date the Pharmacy Guild has run three workshops for community pharmacists and assistants on Smoking Cessation counselling: in November 2014 and August 2015 presented by the Cancer Council ACT; and a March 2015 workshop presented by Dr Colin Mendelsohn from the Australian Association of Smoking Cessation Professionals. Coincidentally, pharmacy assistants were offered extra training on nicotine replacement therapy by a pharmaceutical company in March 2015 which has added value to the Program. Further training by the Cancer Council for both pharmacists and assistants is planned in the near future.

The ACT Community Pharmacy Smoking Cessation Program

Uptake by ACT pharmacies is increasing, with 52 pharmacies across Canberra implementing the Program as of August 2015. Over 200 pharmacists and assistants have completed face-to-face smoking cessation counselling training and many others have undertaken online training. All pharmacies in the Program have reported they are implementing the training with their customers. Smokerlyzer® devices were provided to an initial seven pharmacies and a further seven have purchased their own devices.

Pharmacies have recorded over 317 completed 'profiles' of smokers who are ready to seriously attempt quitting and report that the rate of customer engagement is increasing. Pharmacists often assist customers in managing health conditions which are exacerbated, or caused, by smoking and have said it makes sense to help these customers achieve better health outcomes through quitting.

Some interesting anecdotes have also emerged. One customer (a heavy smoker), and his wife (a non-smoker) were encouraged by one pharmacist to take a reading with the Smokerlyzer®. When the results showed that both of their carbon monoxide results were very high, the smoker made an immediate decision to quit.

Some pharmacies are also reaching out to other health professionals, including GPs and dentists in their area to advise them of the availability of the service. This is beginning to generate referrals both ways, creating a 'circle of care' for patients who are looking for advice and support to quit smoking. The Pharmacy Guild is also fielding enquiries of interest from pharmacies outside the Canberra region.

The training provided and resources available will enable ACT pharmacies that have participated in the training to continue to offer this program in the future. Pharmacies which have so far not undertaken to incorporate the Smokerlyzer® model, piloted in seven target pharmacies, will be provided with evidence of the benefits of the Smokerlyzer® screening, and encouraged to adopt the program fully.

The outcomes of the Program to date have demonstrated that face-to-face smoking cessation counselling in the pharmacy setting can have a positive impact on the health of the community.

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The food-medicine interface

Claire O'Brien, Environmental Health Policy and Projects, Population Health Division

The distinction between food and medicine is becoming increasingly blurred. There are a number of reasons for this, including an increase in products primarily marketed as food that contain ingredients considered to be therapeutic goods. There has also been a boom in the medicalisation of food, whereby advertising increasingly portrays certain foods as a type of medicine. This can lead to confusion as to whether a product should be regulated as a food or a therapeutic good. This article outlines the issues that led to the development of a regulatory tool to assist in differentiating which regulatory framework these products should be regulated under, as well as providing several publicly documented examples of products that fell into the regulatory grey area known as the food-medicine interface.

Food or medicine? What is the food-medicine interface?

The famous Greek physician Hippocrates is quoted as saying '*let your food be your medicine and medicine be your food*'.[1] This quote is particularly apt when looking at the regulatory distinction between food and medicine – a distinction that is increasingly difficult to make.

In Australia, products for oral consumption are generally regulated either:

- as foods (under the Australia New Zealand Food Standards Code and relevant state and territory food legislation); or
- as therapeutic goods (under the *Commonwealth Therapeutic Goods Act 1989* (the Act) and relevant state and territory legislation).

Image: Juggling food and medicine. Iosphere.FreeDigitalPhotos.net

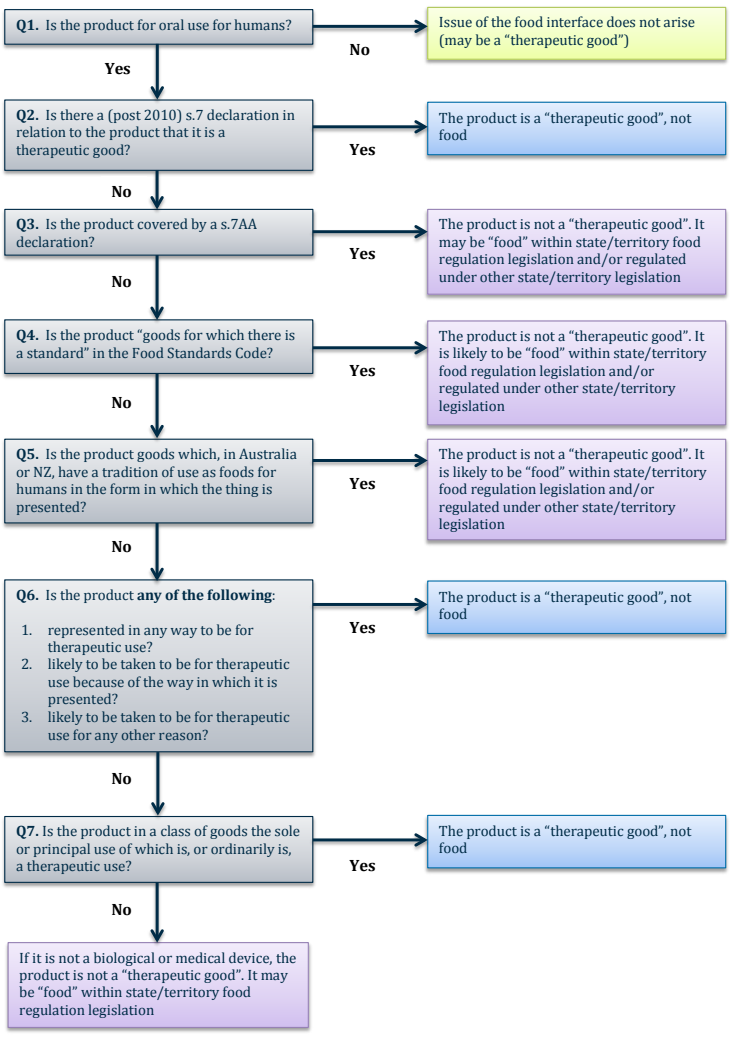
Products that are therapeutic goods are specifically excluded from being regulated as food under food legislation (i.e. state and territory food legislation and the *Food Standards Australia New Zealand Act 1991*). Products that are foods are specifically excluded from being regulated as therapeutics goods under the *Therapeutic Goods Act 1989*. Despite this, it can be unclear whether a product falls under the food or the therapeutic goods regulatory framework. Such products are said to sit in the food-medicine interface.

Uncertainty about the regulatory status of a product could pose a public health risk if the uncertainty delays the taking of appropriate regulatory action. Additionally, if action is taken under the wrong legislation, the producer of an unsafe product could avoid being penalised based on a legal technicality (clearly an undesirable outcome). To minimise any potential health risks and the likelihood of technical legal issues occurring, a timely and consistent national approach is required.

Development of the Food-Medicine Interface Guidance Tool

In recent years, determining whether certain products are foods or therapeutic goods has become more complex for regulators, manufactures, importers and consumers. The introduction of a national health claims standard for foods is thought by some to have further facilitated food medicalisation.[2,3] In January 2013, Standard 1.2.7 – Nutrition Health and related Claims of the Food Standards Code came into effect, allowing some food products to carry health claims (e.g. certain high fibre cereals can claim that 'wheat bran fibre increases stool weight and reduces intestinal transit time'). These claims are not permitted to be therapeutic in nature – meaning that they cannot refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition. However, clever marketing and the breadth of claims available has made this a more complex space for consumers and regulators.

In 2014, the Food-Medicine Interface Guidance Tool (FMIGT) was introduced by the Therapeutic Goods Administration (TGA) in consultation with the Implementation Sub-Committee for Food Regulation (ISFR) Food Medicine Interface Working Group. The FMIGT aims to assist manufacturers, importers, consumers and regulators to understand which regulatory framework should be used to regulate a product.[4] The FMIGT includes an interactive flowchart comprising a series of questions to assist agencies, manufacturers and importers to identify whether a product is to be regulated as a food or as a therapeutic good.



Food-medicine Interface Guidance Tool diagram

The food-medicine interface

It is important to note that the FMIGT does not provide advice as to whether a product complies with requirements of either regulatory framework. It simply identifies the appropriate regulatory category for the product (i.e. food or medicine).

Examples of the food-medicine interface

The challenge of distinguishing between food and medicine is particularly difficult when products traditionally regulated as foods have therapeutic goods added to them. For instance, in May 2014, Food Standards Australia New Zealand (FSANZ) facilitated the recall of an energy drink powder called Dexaprine XR powdered supplement due to the presence of prescription-only medications, including oxedrine (a stimulant) and high levels of caffeine.[5] The product was distributed through sports supplement stores in the ACT, NSW, SA, WA, Victoria and Queensland and via online sales.

At the time of the recall, one person in Australia was reported to have been hospitalised after consuming the drink.[6] It was known that the product contained ingredients that fell within the ambit of therapeutic goods regulation. However, as the product was a formulated supplementary sports food (for which a specific standard is in place under the Food Standards Code), regulatory action was initiated under the food regulatory framework. While regulating this product as a food may not be the obvious *prima facie* solution, the regulatory approach taken is consistent with the application of the FMIGT.

There have been several other examples of traditional food items containing prescription-only medicines that have also been found to fall under the domain of food regulation. For example, Leptin Slimming Coffee[7] and Leptin Weight Loss Chocolate[8] were both subject to recalls in 2010 due to the presence of the now banned prescription weight loss drug sibutramine (although this was not declared on the label). Similarly, in 2011, FSANZ issued a consumer warning about two coffee products (Sexpresso and Rock Hard) that contained sulfoaildenafil, an analogue of the sexual performance enhancing drug sildenafil (more commonly known as Viagra®). The drug content was not declared on the label.[9] At the time, consumers were advised to report similar suspicious food products to their local food regulators.

Photograph: Chocolate and coffee. Dan. FreeDigitalPhotos.net

These examples do not mean that all products that are labelled with 'food like' words fall under food regulation. For instance, in 2013 Vigor Tea sachets were being sold online and in adult shops in Australia. Just like Sexpresso and Rock Hard, Vigor Tea was found to contain undeclared sulfoaildenafil.[10] The tea was advertised as an 'herbal aphrodisiac known to improve libido, desire and energy'. The herbs in Vigor Tea were not traditional constituents of tea in Australia. As such, the product did not have a tradition of use as food for humans in the form in which they were presented. Under the FMIGT, this meant that the product was not a food, and regulation was initiated by the TGA. The TGA issued a safety advisory and worked with Australian Customs and Border Protection Services to help stop future shipments entering Australia.

As these examples show, the food-medicine interface is highly complex. The regulatory approach taken is dictated by case specific details that are often not obvious to outside observers. The ongoing push for product innovation will continue to test the boundaries of the current regulations and will likely require regulators to keep adjusting their approaches and legislative frameworks. Legal actions will also better test the legislation and provide more certainty through precedents.

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Section Highlight

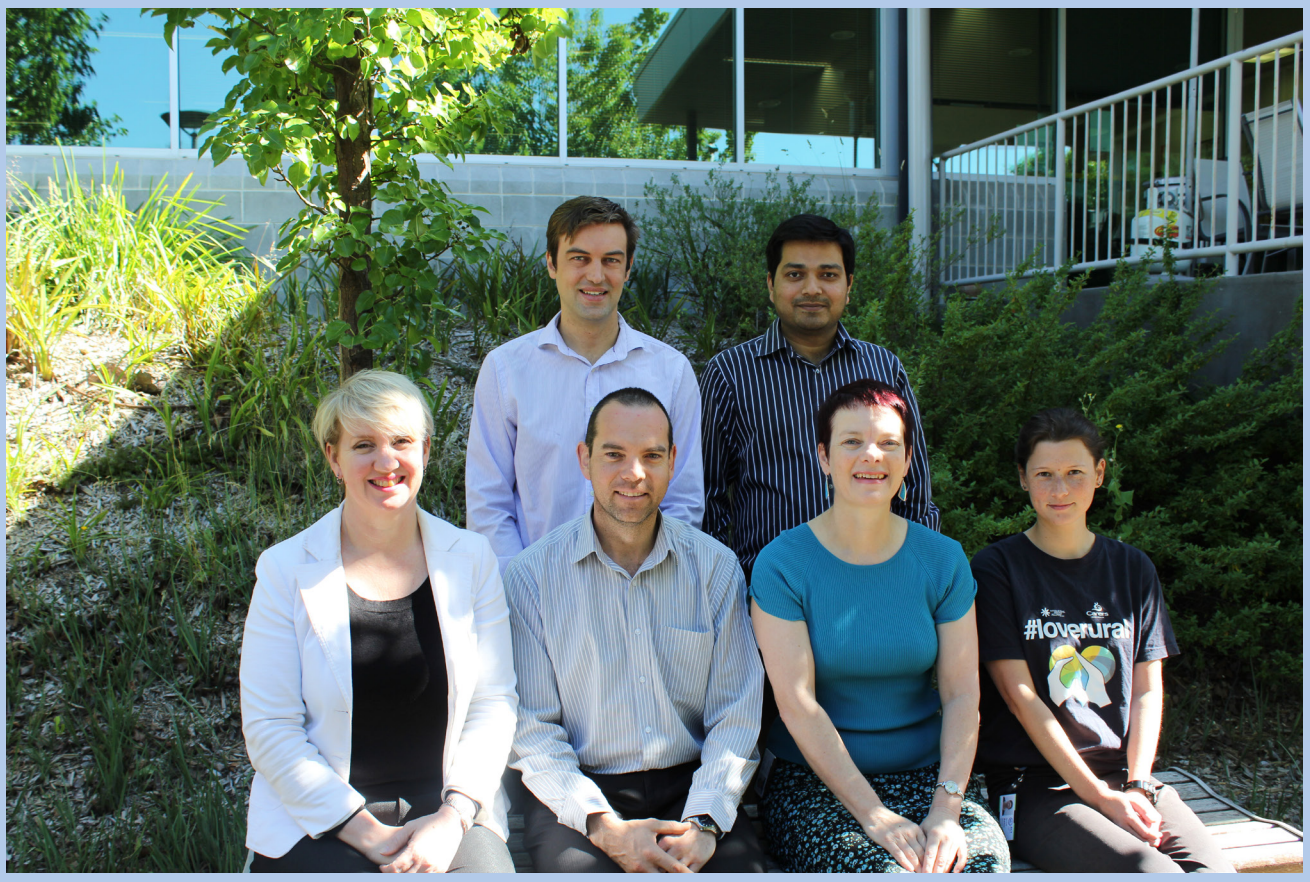
Pharmaceutical Services Section

The role of the Pharmaceutical Services section of the Health Protection Service (HPS) is to ensure the safe supply of medicines, poisons and therapeutic goods to the ACT community.

The section is responsible for conducting a range of regulatory activities for ensuring that medicines and/or poisons are prescribed, stored, administered and supplied safely and in accordance with local legislation. The section is also responsible for licensing, inspecting and regulating community pharmacy ownership and premises in the ACT.

The Pharmaceutical Services section also distributes information across the ACT community about medicine and therapeutic goods recalls, to ensure that the public is protected from any harm from the use of sub-standard or unsafe products. This is, at times, part of a national recall event.

The PSS consists of the Chief Pharmacist, Senior Pharmacists, a Pharmaceutical Inspector, a Senior Policy Officer and a DAPIS Data Administrator. The team has grown significantly over the past few years due to the growth in workload arising from the improved monitoring of controlled medicines authorisation and supply in the ACT.



Photograph: **Pharmaceutical Services Section.**
Back L-R: Adam Duffy, Kapildev Parikh.
Front L-R: Renae Beardmore, Michael Fitzsimons, Cathy Beckhouse, Miranda Batten
Not pictured: Vivien Bevan

To contact the Pharmaceutical Services section contact 6205 1700 or email hps@act.gov.au.

Notifiable Disease Report

Number of notifications of selected notifiable diseases received in the Australian Capital Territory between January – September 2015.

	YTD 2015	1st QTR 2015	2nd QTR 2015	3rd QTR 2015	5 year average YTD (2010-14)	Ratio of YTD: YTD average	2014	5 year average annual total (2010-14)
VACCINE PREVENTABLE CONDITIONS								
INFLUENZA A	472	72	86	314	425.6	1.1	1167	468.6
INFLUENZA B	661	13	42	606	85.4	7.7	97	100.4
MEASLES*	2	1	1	0	3.3	0.6	7	6.0
MENINGOCOCCAL DISEASE (INVASIVE)*	2	1	0	1	1.8	1.1	2	1.8
MUMPS	4	1	0	3	2.2	1.8	2	2.2
PERTUSSIS*	353	88	136	129	309.2	1.1	233	487.2
PNEUMOCOCCAL DISEASE (INVASIVE)	15	1	5	9	16	0.9	15	21.4
RUBELLA*	1	0	1	0	1	1.0	0	1.0
GASTROINTESTINAL DISEASES								
CAMPYLOBACTERIOSIS	410	122	129	159	359.2	1.1	507	481.4
CRYPTOSPORIDIOSIS	15	4	6	5	19.4	0.8	30	22.6
GIARDIA	103	42	28	33	89.4	1.2	148	116.2
HEPATITIS A*	3	1	1	1	2.8	1.1	5	3.6
SALMONELLOSIS	165	93	32	40	161.2	1.0	225	223.4
SHIGELLOSIS	2	0	0	2	5.2	0.4	7	7.8
TYPHOID	1	0	1	0	1.5	1.5	1	2.2
YERSINIOSIS	16	5	8	3	4	4.0	13	5.6
SEXUALLY TRANSMITTED INFECTIONS								
CHLAMYDIA	988	337	333	318	936.2	1.1	1197	1234.2
GONNOCOCCAL INFECTION	112	42	42	28	77.6	1.4	119	101.8
SYPHILIS <2 YEARS DURATION	12	5	1	6	10.6	0.4	18	13.4
VECTORBORNE & ARBOVIRUS								
BARMAH FOREST VIRUS INFECTION	2	2	0	0	3	0.7	1	3.0
DENGUE FEVER*	14	8	0	6	13.4	1.0	16	16.0
LEPTOSPIROSIS	1	1	0	0	1	1.0	0	0.4
MALARIA	5	2	1	2	9	0.6	10	10.6
ROSS RIVER VIRUS INFECTION	8	6	2	0	8	1.0	5	10.0
RESPIRATORY CONDITIONS								
TUBERCULOSIS #	14	5	5	4	13.6	1.0	28	18.8

All Diseases except Tuberculosis are reported by onset date or closest known test date. Tuberculosis is reported by notification date.

* This condition includes cases that meet the probable and confirmed case definitions. Both probable and confirmed cases are nationally notifiable.

For the relevant year, Q1 refers to 1 January to 31 March, Q2 refers to 1 April to 30 June, Q3 refers to 1 July to 30 September, Q4 refers to 1 October to 31 December.

YTD refers to total number of cases in the year to date.

N.B. Data reported are the number of notifications received by ACT Health. Data are provisional and subject to change.

The number of notifications received for all notifiable diseases in the ACT is available at http://www9.health.gov.au/cda/source/cda-index.cfm

HIV data are reported annually by the Kirby Institute: http://kirby.unsw.edu.au/surveillance/Annual-Surveillance-Reports

The influenza season in the ACT in 2015 was dominated by influenza B infection, which was notified 10 times more than the year to date average over the previous five years. In total, there were 1,133 influenza notifications. The median age of cases in 2015 was 34 years and 46 percent were male. Further information about the ACT influenza season can be found at: http://www.health.act.gov.au/sites/default/files//Influenza%20Report%20to%2031%20October%202015.pdf. There was one case of invasive meningococcal Y infection in the third quarter in the ACT. There were no measles infections. There have been 353 pertussis cases notified which is twice as many compared to the year to date average in the previous 5 years. Forty percent (n=144) of notifications were reported in people under 20 years of age, compared to 23% (n=54) in 2014. Fifty-three percent (n=188) of cases were female in 2015. Compared to other years, there are the expected numbers of cases or less cases compared to the year to date average for all the notifiable gastrointestinal diseases except yersiniosis, where the increase is most likely attributable to changing testing methods rather than an increase in disease incidence.

Seasonal outlook for the 2015-16 summer

The summer period in south-eastern Australia sees an elevated risk of the occurrence of natural disasters including bushfire, extreme heat events and severe storms, usually occurring annually from October to March.

The Bureau of Meteorology (BOM) has provided a climatic seasonal outlook for summer. The BOM has advised that the tropical Pacific Ocean and atmosphere are reinforcing each other, maintaining a strong El Niño that is likely to persist into early 2016. Tropical Pacific sea surface temperatures are more than 2 °C above average, exceeding El Niño thresholds by well over 1°C, and at levels not seen since the 1997–98 event. Further information regarding El Niño in Australia is below.

October to December is likely to be drier than average for the ACT and Regional NSW. Warmer days and nights are likely. The current outlook reflects a combination of a mature El Niño in the Pacific, and an emerging positive Indian Ocean Dipole. Heatwaves are likely to be on the increase in terms of frequency for the remainder of spring and summer.

The ACT Extreme Heat Plan details the arrangements for a coordinated approach between ACT stakeholder agencies in response to an extreme heat event. The ACT Ambulance Service (ACTAS) is the designated Lead Agency for response to an extreme heat event in the ACT.

Under the Plan, ACT Health is responsible for providing annual pre-season information and advice to the community, in particular, to vulnerable populations, in relation to measures to take in preparation for summer heat.

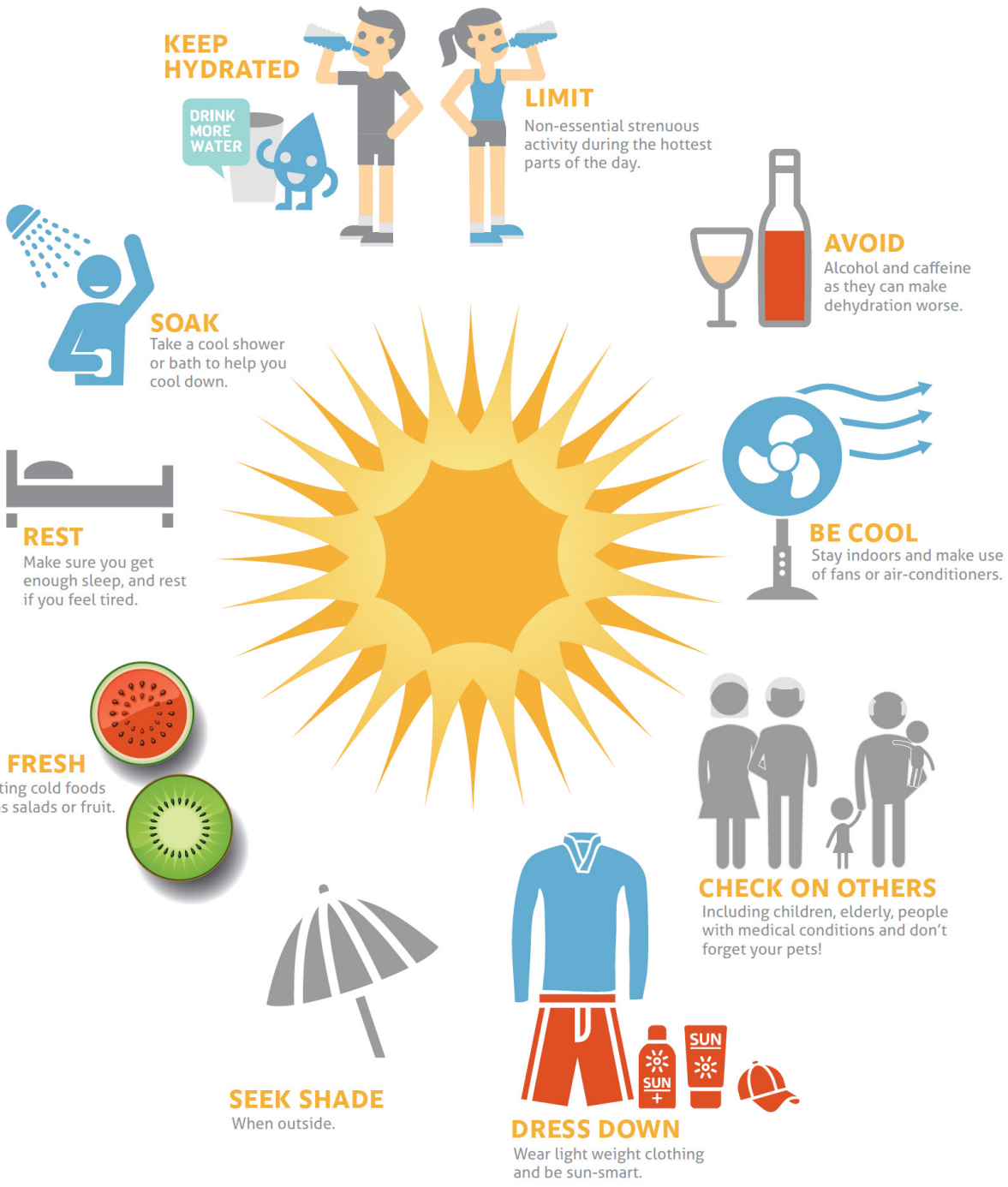
In anticipation of the upcoming 2015-2016 summer season Health Protection Service has reviewed key documents related to extreme heat events and heat-related stress.

The Chief Health Officer has also sent letters to School Principals, Residential Aged Care Managers and Child Care Centre Managers advising them of specific steps to reduce the risk of heat-related stress in children, babies and the elderly at their institutions.

The suite of existing heat stress information sheets have been reviewed and updated. The revised information sheets is available on the ACT Health website.

In addition the heat information graphic titled 'Tips to Beat the Heat' is on page 31 will also be used for the upcoming 2015-16 summer season. This information graphic is available on the ACT Health website and will also be used for social media posts.

TIPS TO BEAT THE HEAT!



WATCH OUT

Be on the lookout for any symptoms of heat related illness.
See your GP if you are unwell.
In a medical emergency call 000.
For more information on extreme heat please visit
http://health.act.gov.au/health-services/population-health/summer-safety

ACT Government Health | CANBERRA HOSPITAL AND HEALTH SERVICES

Hot Issues

Community consultation on outdoor smoke-free areas

The ACT Government is gathering community feedback on options for new smoke-free areas at outdoor places where children may be exposed to second-hand tobacco smoke and smoking behaviours. These places include:

- public play spaces/playgrounds;
- skate parks;
- bus waiting areas;
- public building entrances;
- sporting events; and
- outdoor public swimming pools that are privately-owned.

Community members can have their say on this issue by visiting the Time to Talk website: www.timetotalk.act.gov.au. The consultation is open until 17 December 2015.

Feedback gathered as part of the consultation process will be used to decide on priority locations where smoke-free areas may be established, and to guide implementation arrangements.

Photograph: Swimming pool and Playground. Evgeni Dinev and Feelart. FreeDigitalPhotos.net

ACT Asbestos Health Study

ACT Government has contracted independent researchers from the Australian National University's National Centre for Epidemiology and Population Health (NCEPH) to undertake a study to gain additional understanding regarding the risk of developing mesothelioma from living in a house containing loose-fill asbestos (a 'Mr Fluffy' house).

There are four parts to the ACT Asbestos Health Study (the Study):

- An analysis of mesothelioma rates and distribution in the ACT;
- Focus groups held with current and recent residents of affected houses to discuss their health-related concerns;
- A study looking at the likely exposure levels and health related concerns of current and recent residents in terms of years lived in an affected house and activities such as renovating; and
- A study linking a number of data sets to estimate the risk of developing mesothelioma in current and former residents of affected houses compared with the general population.

The Report into Part 1 of the Study was released on 14 September 2015. Key study findings included:

- Mesothelioma incidence is extremely low in the ACT, but has increased over time. This has also occurred in other parts of Australia.
- Mesothelioma rates were lower on average in the ACT than in the rest of Australia (excluding WA) for the period 1994-2011. There is evidence that over this time the incidence of mesothelioma in the ACT increased at 12% greater rate per three-year period than in the rest of Australia. There is, however, considerable statistical uncertainty about the significance of these results, and they are mostly the result of cases occurring between 2009-2011.

The health risks associated with living in a Mr Fluffy house are the subject of further studies within the ACT Asbestos Health Study, which may provide more evidence regarding the relationship between Mr Fluffy houses and mesothelioma risks.

The full report is available at http://nceph.anu.edu.au/files/ACTAsbestosHealthStudy_Report_Component%201.pdf

Hot Issues

ACT Government continues efforts to make the healthy lifestyle choices the easy choice

The ACT Chief Minister, Andrew Barr MLA, released the first annual report card on the ACT Government's Healthy Weight Initiative in August 2015.

Part of the ACT Government's commitment to support a healthy, active and productive community, the Healthy Weight Initiative is a whole-of-government program which supports the government's goal to keep rates of overweight and obesity in the ACT at or below 2014 levels.

The Initiative sets out a number of actions across a range of environments including shops, schools, workplaces, communities, urban planning and homes.

Significant achievements made under the Initiative in 2014-15 include:

- introduction of the ACT Public School Food and Drink Policy 2015 to promote healthy food and drinks in schools;
- installation of new outdoor fitness stations and walking trails, supported by a Find Fitness Outdoors online hub and marketing campaign;
- delivery of community programs including swimming lessons, cooking demonstrations and fitness sessions for various multicultural and disadvantaged communities;
- implementation of the Good Habits for Life education campaign aimed at changing lifestyle behaviours of families;
- implementation of the Fresh Tastes healthy food at school program for primary schools and the It's Your Move program for ACT public secondary schools;
- installation of 30 drinking water stations across sporting fields, neighbourhood ovals, parks and public spaces, and at least two water refill station at all ACT public schools; and
- Active Living principles incorporated into all town and group centre master plans.

The annual report card also outlines the priority areas for 2015-16 focussing on a range of environments across Canberra.

Even though the ACT population is the healthiest in Australia, almost two-thirds of adults and around one in four children are overweight or obese in the ACT. High levels of overweight and obesity affect everyone and impact our economy and the health system. The ACT Government has made it a priority to address this challenge.

In the 2014-15 Budget the Government committed $3.6m over four years to progress the Healthy Weight Initiative, in addition to existing resources which are being used across government. The Government further committed $2.5m over four years in the 2015-16 Budget to deliver a range of programs supporting healthier lifestyles under the Healthy Weight Initiative, as well as significant infrastructure investment.

The ACT Government's Healthy Weight Initiative annual report card 2014-15 can be accessed at www.act.gov.au/healthyliving.