Submission No 46

INQUIRY INTO DRUG AND ALCOHOL TREATMENT

Organisation: Alcohol and other Drugs Council of Australia

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ADCA
Alcohol and other Drugs Council of Australia

Inquiry into drug and alcohol treatment

by the

New South Wales Legislative Council

22 March 2013

ABN: 39 008 455 525

The Alcohol and other Drugs Council of Australia (ADCA) welcomes the opportunity to respond to the New South Wales Legislative Council's *Inquiry into drug and alcohol treatment*.

ADCA is the national non-government peak body representing the interests of the Australian alcohol and other drugs (AOD) sector. It works with government and non-government organisations, business and the community to promote evidence-based, socially just approaches aimed at preventing or reducing the health, economic and social harm of alcohol and other drugs to individuals and the broader Australian community. This submission has been prepared in consultation with the Public Health Association of Australia and ADCA's Illicit Drugs Working Group.

This submission is supported by the Public Health Association of Australia (PHAA). The PHAA is recognised as the principal non-government organisation for public health in Australia and works to promote the health and well-being of all Australians. The Association seeks better population health outcomes based on prevention, the social determinants of health and equity principles.

Background

Since the launch of the National Campaign Against Drug Abuse in 1985 and the subsequent National Drug Strategy, Australia has adopted a harm minimisation approach to reduce the impact of alcohol and other drugs (AOD). In so doing, it does not take a position on whether drug use is good or bad, rather it recognises that people will choose to take drugs regardless and focuses on reducing the harm associated with that use. ADCA supports the principle of harm minimisation.

Alcohol and illicit drug use contributes to 5.4% of the global burden of disease[i]. Of all drugs used in Australia, alcohol is the most widely used[ii] and is one of three prevention targets that have been set by the Australian National Preventative Health Agency [iii].

Excessive alcohol consumption is a major risk factor for morbidity and mortality and alcohol related harm was estimated at 3.2% of the total burden of disease and injury in Australia in 2003[iv]. The total social cost of alcohol abuse in Australia including harm to others is estimated at $36 billion[v]. Children, families and friends often bear the consequences of another person's consumption and can be subjected to violence, injury, prejudice, stigma and shame.

A number of strategies have been adopted in Australia to reduce the harms associated with alcohol use, however the most effective policies to prevent alcohol related harm have not been implemented. ADCA's key priorities for alcohol relate to increasing the price through the introduction of a minimum price for alcohol and reform of alcohol taxation to a volumetric based tax for all alcohol products, reducing access and availability, and restricting advertising and promotion.

NSW has seen a number of Inquiries and activities in the past 12 months that are related to alcohol and other drugs. The Office of Liquor Gaming and Racing engaged the Allen Consulting Group to look at the impact of outlet density, there have been Inquiries into law reform issues associated with synthetic drugs, the provision of alcohol to minors, the medical use of cannabis, strategies to reduce alcohol abuse among young people, and the Coroner's Inquiry into the deaths of three young people following treatment with naltrexone implants, and there have been a number of initiatives introduced following the death of Thomas Kelly in July. Last week an alcohol summit was held by the NSW ACT Alcohol Policy Alliance (NAAPA). Other states and territories have been undertaking similar activities and likewise at a federal level.

Inquiries such as this one into drug and alcohol treatment need to take into consideration the various findings of such activities and be conscious of the context in which the Inquiry is occurring. Action needs to be taken that is informed by the evidence and focused on health outcomes.

It is surprising to be responding to an Inquiry that suggests using naltrexone implants so quickly after the state Coroner strongly endorsed the position and recommendations of the Australian National Council on Drugs which recommends that clinical trials be conducted as soon as possible to determine the safety and efficacy of naltrexone implants. The ANCD paper also makes the comment that continued use through the Special Access Scheme is ethically problematic as it puts patients at risk.

The response by the NSW government to Thomas Kelly's death last year has focused mainly on responding to the problems but hasn't addressed the drivers of those alcohol related problems. The alcohol summit held last week by the NSW ACT Alcohol Policy Alliance (NAAPA) called on the government to 'to embrace proven, evidence based policies to prevent and reduce alcohol-related harms'. At this stage there has been little response. What is needed is a commitment by the NSW Government to restrict advertising and promotion, reduce outlet density and trading hours, and support the work of the police, paramedics and emergency workers, and doctors, nurses and other hospital staff to reduce alcohol related harm. As the NSW Police Force Commander for the central metropolitan region said at the forum, "Alcohol takes up more time, more effort, more money, more resources than anything else.'

There has been growing interest worldwide in reconsidering our approach to illicit drug use with prominent politicians and businessmen calling the so called *War on Drugs* a failure. Closer to home, Australia21 released two reports in 2012 calling for a rethink of our policies in relation to drug law enforcement and groups like Families and Friends for Drug Law Reform and the Australian Drug Law Reform Foundation have been calling for drug law reform for years.

ADCA offers the following comments in relation to the Terms of Reference for his Inquiry.

The delivery and effectiveness of treatment services for those addicted to drugs and/or alcohol, including naltrexone treatment, with reference to the welfare and health of individuals dependent on illicit drugs and the impact on their families, carers and the community.

Treatment for people with drug dependence is one of the most effective and cost-efficient responses available to governments[vi]. Treatment has the ability to provide individuals, families and communities with opportunities to humanely and safely address drug dependence issues[vii]. Interventions and strategies exist to prevent and treat substance use disorders however political will and sufficient resources are required for them to be implemented and be effective. Currently in Australia there is considerable demand for services and waiting lists are long. Clients may wait up to 5 years before they can receive appropriate treatment[viii].

Drug use is preventable and treatable and therefore investment in prevention, early intervention and treatment has the potential to create significant benefits to society in terms of reducing health related costs, improving security and contributing to social cohesion and development[ix].

Recognising that AOD use sits on a continuum of intermittent use to severely dependent, it makes sense that there is a continuum of need in relation to support and treatment required. Add to the mix different personalities and level of commitment to treatment and it is easy to see that an approach that works for one person may be totally inappropriate for another. Hence an array of treatment options is required and expectations need to be tempered by an understanding of where an individual is at in relation to their treatment journey.

The Australian National Council on Drugs held a roundtable in August last year on medication-assisted treatment for opioid dependence (MATOD). The Roundtable Report[x] recognises and reinforces the value and appropriateness of including medically assisted treatment within a comprehensive treatment system. It made note of some of the issues and concerns associated with medically assisted treatment, of particularly relevance to this section being those related to access and resources, and next steps associated with improving the reach, effectiveness, and efficacy of the MATOD program.

In relation to the specific use of naltrexone treatment, naltrexone is used in the management of alcohol and opioid dependence[xi]. It was approved for use in Australia in oral form and by prescription. As with most if not all medications, the effectiveness of oral naltrexone among opiate users is significantly reduced by non compliance[xii].

Injectible naltrexone and naltrexone implants were developed overseas in an effort to address non compliance with oral naltrexone. These formulations offer a slow release medication regime which is longer lasting. They have not been approved for use in Australia except under very specific circumstances, but recent concerns about of the treatment suggests that any use should be withdrawn until further research is conducted meeting NHMRC scientific and ethical standards to demonstrate safety and efficacy. ADCA does not support the use of naltrexone

implants in Australia until this has been achieved. This submission discusses naltexone implants in more detail below in the final term of reference.

Many people will want to have the support of their family or friends when seeking treatment and it is important to make sure that services are willing and able to accommodate these needs. Family support has been shown to be one of the strongest factors in successfully dealing with the effects of alcohol and other drug (AOD) use[xiii]. Where support from families and/or friends is wanted, it is important that they are involved in the planning and provision of ongoing support both during and after treatment.

Families often suffer the consequences of AOD use by a family member. Those consequences can stem from lack of involvement in treatment processes, but also lack of coordination between appropriate services, the shame and stigma attached to substance use, and the flow-on from laws and policies. The impact on family members can vary according to the individual nature of their relationship (ie. parent, sibling, child) and may need their own support while working with their family member's drug usage and treatment.

Drug users and their families and friends are often stigmatized and discriminated against which has a negative impact on treatment progress. Prejudice, stigma, shame, derogatory language and the many myths associated with drug use are counterproductive to seeking help by both the family and the user. These can also affect the quality and standard of health services. Staff providing such services need to consider potential barriers within their own organisations and where appropriate, work to overcome them. Furthermore as a community, we need to have understanding and empathy for drug users and their families and provide support to them.

The level and adequacy of funding for drug and/or alcohol treatment services in NSW

Historically, the level of funding available to the AOD sector across Australia is inadequate. Furthermore, the current capacity of drug treatment is grossly inadequate. Existing evidence-based treatment services are underfunded and lack the capacity to keep pace with demand.

Capacity should be large enough to accommodate all people who want access to effective, evidence-based treatment and should be of the same high quality as any other part of the health system, offering a range of treatment options in both the government and non government sectors that are more attractive, flexible and affordable than those currently available.

ADCA understands that recent decisions affecting the NSW alcohol and other drugs sector may see approximately 55 organisations defunded, further reducing the availability of services in a sector that was already seriously under resourced and under serviced. This will result in more people having problems with their alcohol and other drug use and those problems becoming more complex before treatment is available. Innovative approaches will be stifled further.

Across Australia, the majority of funding provided to support the National Drug Strategy is spent on drug law enforcement compared to treatment and prevention. The consequences arising from heavy reliance on law enforcement and the criminal justice system have contributed to community attitudes which are counterproductive to family members and consumers seeking support. Generally people using AOD are reluctant to speak to family members about their illicit drug use and do not seek treatment because of the stigma associated with it. Additionally some treatment service personnel do not recognise that addiction is a chronic relapsing disorder which further contributes to user stigmatisation.

Policy emphasis should shift towards health and human rights, noting that more effective responses to illicit drug problems require a primarily health and social approach. Health and social approaches are more effective, have fewer unintended negative consequences and are more cost-effective. Evidence based approaches are critical for success in dealing with the use of illicit drugs and the growing problem of pharmaceutical misuse.

Rather than cutting services back, drug treatment needs to be expanded and improved to meet the needs of those seeking treatment and based on scientific evidence for efficacy, safety and cost-effectiveness.

The following services are needed to ensure that NSW has a treatment sector that provides a range of treatment options to meet the needs of clients and is effective in reducing harm:

1 heroin assisted treatment

Research has consistently found major improvements in physical health, mental health and social well-being (including less crime) for those that benefit from HAT[xiv]. Further research to support HAT is not required.

Prescribing heroin for the treatment of addiction has been occurring over the past century, mostly in the UK. S*upervised* injectable heroin treatment, also known as heroin assisted treatment (HAT), has been provided in Switzerland over the past 15 years or so, as a second-line treatment for entrenched heroin addicts for whom previous orthodox treatments such as oral methadone maintenance treatment (MMT) or residential rehabilitation have produced little benefit. A similar approach could be adopted in NSW and indeed the rest of Australia. HAT is now available in five countries.

2 overdose witness-administered naloxone

Naloxone is an opioid antagonist which offers an effective and safe method of quickly reversing the effects of heroin overdose when used medically. Numerous observational studies suggest that naloxone distributed to potential overdose witnesses, including drug users and their family members, may reduce the number of heroin overdose deaths. There is strong support for naloxone distribution to potential overdose

witnesses[xvxvi] and programs to make naloxone available to Australian opioid users on prescription have recently commenced.

The effectiveness of mandatory treatment on those with drug and/or alcohol addiction, including monitoring compliance with mandatory treatment requirements

ADCA does not support the use of mandatory treatment except in extreme circumstances where a person's capacity to make decisions is diminished and they are at risk of injuring themselves or someone else. Note that diminished capacity to make decisions may change during treatment and should be reassessed over time.

Further, involuntary treatment should continue only for the minimum time needed to re-establish capacity and safety for the individual, and to ensure they have the appropriate support once they leave involuntary treatment. This is critical to increase the chances of success for the individual and free up resources for other clients in a sector where resources are stretched. At all times consideration should be given to the human rights of individuals - appeal provisions are needed to protect individuals who are involuntarily admitted for alcohol and other drug treatment. In 2011 the Queensland Government recognised the lack of evidence to support the efficacy, safety and cost effectiveness of involuntary treatment in its information paper for the *Inquiry into severe substance dependence: a model for involuntary detoxification and rehabilitation* by the Health and Disabilities Committee[xvii].

Evidence based approaches are critical for success in dealing with the use of illicit drugs and the growing problem of pharmaceutical misuse. The money spent on establishing and running an involuntary detoxification and rehabilitation program would be better spent on providing services to the community that are known to be effective and address fundamental issues that contribute to alcohol and drug related harm. Success in this area would lead to fewer people becoming severely dependent.

Existing evidence-based treatment services are already being defunded and those that still receive government funding are underfunded and lack the capacity to keep pace with demand. A shrinking service sector combined with an increase in the number of people seeking treatment should mandatory treatment be enforced would result in longer waiting lists for people seeking to engage with treatment voluntarily.

The adequacy of integrated services to treat co-morbid conditions for those with drug and/or alcohol addiction, including mental health, chronic pain and other health problems

It has long been acknowledged that people with complex needs often fall through the cracks in service delivery – between national and jurisdictional service delivery, between government and non-government services, and between services delivered by different portfolio agencies. Successful collaborative efforts in service delivery are possible and are occurring across Australia. However, more work needs to be done to improve outcomes for people with complex needs.

Mental health is but one area of co-morbidity for alcohol and other drug users. While the recent focus on mental health co-morbidity is welcome, it has overshadowed other co-morbidities such as tobacco, which is a much bigger problem that mental health co-morbidity. Changes in states like Queensland have seen the alcohol and other drugs sector absorbed by the bigger and better resourced mental health sector. While there are many close connections with mental health, the alcohol and other drugs sector is quite different. Physical health co-morbidities, especially injury and brain damage, need far more attention than they now receive.

Close collaboration between sectors is very important to address the range of issues that a person may present with. The difficulty lies with having adequate resources to allow the collaboration to take place without perceptions of amalgamation or rationalization savings. Working with other sectors and people within those sectors takes time and requires trust to be established. For each client it is important to help establish those relationships so that they can have confidence that there needs are understood and dealt with in the context of other treatment that is taking place. Treatment works, but needs time and effort to achieve positive outcomes.

The funding and effectiveness of drug and alcohol education programs, including student and family access to information regarding the legal deterrents, adverse health and social impacts and the addictive potential of drugs and/or alcohol

ADCA would like to express its concern at the closure of the drug education unit within the Education Department. Young people need to be informed about drug issues because they live in a world in which drug use is ubiquitous[xviii].

There has been some discussion about the effectiveness of drug education programs in schools. A literature review by the National Centre for Education and Training on Addiction (NCETA) found that:

- the most successful drug education programs in schools tended to use a social influence approach (which aims to teach young people to avoid taking drugs by resisting peer pressure to do so and by increasing coping skills, rather than a competence enhancement approach),
- include wider community and parental involvement, and
- address the whole school environment, promoting positive relationships and behaviours, reducing victimisation and bullying and increasing social connectedness.

A recent project in Victoria provides evidence to support the effectiveness of well planned, evidence based education programs for schools. The Victorian Department of Education and Early Childhood Development, Edith Cowan University; Research Centre and The University of Melbourne have developed the Drug Education in Schools (DEVS) curriculum that addresses issues around the use of alcohol and other drugs to Year 8 and 9 students.

However drug education should be part of a broader strategy to prevent or delay drug use. The successful tobacco campaign, for example was a vast intervention that eventually included school education, social marketing, taxation, advertising and marketing controls, and smoking restrictions.

Preventing early use and delaying use is an important outcome because research indicates early use of alcohol, cannabis and other illicit drugs predicts subsequent risk of problematic use and dependent use[xix]. In the case of tobacco, preventing early use is crucial because most smokers take up smoking during adolescence and comparatively few begin in adulthood. If school drug education prevents initiation of alcohol and illicit drugs use by even a year or two it may also reduce subsequent problematic use that can cause severe disruption to young people's lives by affecting their mental health, education and future career prospects and family and social relationships. As the risks attached to drug use escalate the earlier drug prevention begins, the more likely it is to reduce short and long term harm.

A harm reduction approach has been adopted by Australian secondary schools for alcohol, although not for tobacco or illicit drugs. The harm reduction approach is supported by a systematic review of universal multi-drug education programs carried out by Foxcroft & Tsertsvadze (2012)[xx] that found *reduced* 'binge drinking' was a more likely outcome of drug education than *abstention* from alcohol by young people. This has been borne out by some Australian programs.

Apart from formal drug education, schools can reduce many personal and social risk factors that predispose young people to drug use and promote those protective factors that lessen the likelihood of drug use. Those factors include connectedness with school, positive peer and adult relationships, and a strong sense of future prospects[xxi]. A whole school health promotion approach was adopted by the Gatehouse Project that promoted students' emotional and behavioural well-being, improving staff-student relationships and students' relationships with their peers to promote a sense of wellbeing and security, so that students felt accepted and worthwhile and able to learn. Among other results, alcohol and tobacco use among the students fell by 3–5% respectively, highlighting the effect schooling has on young people's health status[xxii].

For drug education to be effective however, schools need systematic and ongoing support[xxiii].

The strategies and models for responding to drug and/or alcohol addiction in other jurisdictions in Australia and overseas, including Sweden and the United Kingdom.

ADCA supports an evidence based approach to providing treatment for alcohol and other drug users. Australia's National Drug Strategy adopted a harm minimisation approach at its outset nearly thirty years ago in recognition that people will choose to take drugs regardless of their legal status. The National Drug Strategy therefore focuses its attention (in addition to efforts

around demand and supply reduction) on reducing the harm associated with their use and employs a range of strategies to achieve this. It recognizes that there is no 'one size fits all' regarding treatment, that people are at different stages in terms of addressing their drug use and that they need support for their recovery towards stable and self directed lives. It does not dictate whether clients are drug free at the end of their treatment. It recognises that addiction is a chronic, relapsing illness that is difficult to cure[xxiv]. ADCA strongly supports the principle of harm minimisation and harm reduction.

Sweden has had a relatively long history in relation to an abstinence based drug policy. Its aim is to achieve a drug free society and places heavy emphasis on drug law enforcement efforts. Other strategies used in Sweden to achieve its goal include prevention and treatment; harm reduction has not been a feature of Swedish policy until recently although it this recent attention is only focused on alcohol[xxv]. Zero tolerance for narcotics remains.

Besides the overall objective of a drug free society, the strategy contains seven long-term objectives. ADCA supports these objectives in principle and particularly supports the objectives around reducing the number of people who become involved in harmful use and improving access by people with abuse or addiction problems to good quality care and support. However, ADCA supports the approach taken by Australia's National Drug Strategy to addressing issues around alcohol and other drugs, incorporating harm reduction, rather than the restrictive approach in place in Sweden.

The United Kingdom has also moved towards a policy that aims for all clients to be drug free. In late 2010, the United Kingdom introduced its new drug strategy *Reducing demand, restricting supply, building recovery: supporting people to live a drug free life*. While recognizing that 'the causes and drivers of drug and alcohol dependence are complex and personal' and that 'The solutions need to be holistic and centred around each individual' it rejects the notion of harm reduction. As a consequence, funding is centred around services that aim to have clients drug free at the end of treatment and a payment by results approach has been introduced that only pays services for a client if that client is drug free six months after treatment.

This approach is counter-productive to achieving success in helping people to reduce their dependency on drugs and live productive and successful lives. It puts people's lives at risk. It does not recognise the important public health role played by many harm reduction services such as needle and syringe programs (NSPs) which have been supported by the Australian Government since its inception in 1987 and has been instrumental in preventing the spread of blood borne viruses[xxvi]. It recognizes neither that there is a need for flexibility in services to meet different needs, nor that the journey from dependence to stability is less than straightforward. Furthermore, it does not recognise that harm reduction measures such as methadone maintenance treatment, NSPs and medically supervised injecting facilities provide opportunities for referral and can contribute to the journey of achieving stability.

The payment model adopted creates tremendous uncertainty for services and runs the risk that services will only take on clients that are likely to respond to treatment, and refuse those that

are more complex and more vulnerable. In essence, it works against what the government is trying to achieve and means that those that need treatment most will be the ones least likely to receive it.

Note that care should be taken in looking at the terminology used in UK and comparing it to Australia. Recovery in the UK has a different meaning to the way in which it is used here in Australia. Both recognise the importance of the need to look at the broader picture of the individual in terms of their health, housing, education, employment, relationships and other issues. However, in the UK the term recovery is based on an abstinence goal whereas in Australia the aim is to achieve stability and self directed lives. Methadone maintenance for example is significant in reducing the risk associated with complete abstinence for opioid users - abstinence would be a high risk strategy for some of these clients and would be a high risk strategy for a government to impose.

Looking at the bigger picture, drug use (apart from alcohol, tobacco and registered pharmaceuticals), is an illegal activity in Australia. There have been calls for change in both the UK and Australia and indeed around the world[xxvii], calling for a rethink on our drug laws and the heavy emphasis on law enforcement which causes further harm.

A shifting of the focus from a law enforcement to health and human rights approach is needed together with a shift in the associated resources. Policies that combine a public health and social approach, with reduced criminal penalties appear to be associated with the greatest gains across both health and criminal justice domains[xxviii]. Prevention, early intervention and treatment are all critical components of our response to alcohol and other drug usage and need adequate funding so that the demand for treatment of more complex and severe cases of dependence (which are much more expensive to provide) can be met and decline over time.

The proposed reforms identified in the Drug and Alcohol Treatment Amendment (Rehabilitation of Persons with Severe Substance Dependence) Bill 2012

This draft Bill proposes to enable use of naltrexone implants for persons with alcohol and drug problems in an outpatient setting as an alternative to being detained for compulsory treatment. This is a surprising and worrying proposal. Naltrexone implants are not yet approved for use in Australia and are only able to be used in specific circumstances (ie when the patient is seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment[xxix]). It is even more concerning given the findings of the recent NSW Coronial Inquiry into the deaths of three people after being treated with naltrexone implants at a Sydney clinic and the 2011 review of the evidence by the NHMRC which recommended that this treatment *only* be used within the context of a clinical trial.

The NSW Coroner strongly endorsed the statements and recommendations of the ANCD position statement on *Naltrexone sustained release preparations (Injectible & implants)* which is attached for your information. Naltrexone implants should not be used in Australia outside research trials until they meet full TGA requirements including effectiveness and safety.

In discussing the findings of the NHMRC literature review, the report recommended caution in interpreting the results of the studies examined as 'the sample sizes were small, duration of treatment and follow-up was inadequate, the comparators are inappropriate and many studies report on the same base cohort.[xxx]' The report made the following findings.

In relation to **effectiveness**, the review found:

- significant reductions in opioid use and hospital admissions in the implant groups as well as a significantly higher treatment retention rate and improved quality of life (selected measures – work, satisfaction, family/social relationships), and
- no significant difference between implant and control groups in relation to criminal activity or use of non-opioid drugs.

In terms of **safety**, the review:

- found inconsistencies in reporting on mortality in some trials, and
- recommended further research on adverse effect s before a statement on safety could be confidently made

Reflecting the mixed results in the **research**, the review identified that research into the efficacy and safety, as well as cost effectiveness, of naltrexone implants is needed

The report recognised that naltrexone implants may show some efficacy as part of an integrated program. However the report went on to say that more research is needed: 'Naltrexone implants are an experimental product and as such should only be used in the context of a well conducted randomised control trials with sufficient sample size, appropriate duration of treatment and follow up, regular robust monitoring, provision of a comprehensive psychosocial treatment program, and with comparison to current best practice. Until these trials have occurred and the relevant data are available and validated, the efficacy of the treatment, alone or in comparison to conventional first line treatments, cannot be determined'. The report noted the vulnerability of many opiate dependent people and the pressure they can be under from family, friends and the authorities to participate in treatment

Until this research is undertaken and the efficacy and safety of naltrexone implants is established, ADCA considers that use of naltrexone implants as a treatment for people with alcohol and other drug problems is a high risk strategy that cannot be supported.

Furthermore, ADCA does not support the use of compulsory treatment except in very specific circumstances and it does not support an increase in the maximum time that a person can be involuntarily detained. Indeed, as mentioned earlier, involuntary treatment should continue

only for the minimum time needed to re-establish capacity and safety for the individual, and to ensure they have the appropriate support once they leave involuntary treatment.

Closing comments

ADCA would like to once again express its appreciation for the opportunity to provide comment to the Inquiry and makes the above comments as part of a constructive process to seek feedback on the proposal. However, it has to be said that it is not clear why the government would seriously consider the use of a treatment that has not yet been fully evaluated, whose efficacy and safety has not yet been established, and against the recommendations of the NHMRC and the findings of the recent Coronial Inquiry into the deaths of three young people administered naltrexone implants.

I would be happy to talk about this further with the Inquiry should you wish to do so. Please contact Meredythe Crane in the first instance.

Yours sincerely

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Chief Executive Officer

22 March 2013

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AUSTRALIAN NATIONAL COUNCIL ON DRUGS

ANCD POSITION STATEMENT

Naltrexone Sustained Release Preparations (Injectible & Implants)

March 2012

In response to the ongoing debate regarding the use of Naltrexone implants to treat opioid dependence, the Australian National Council on Drugs, as the principal advisory body to the Federal Government on drug and alcohol policy and programs, has released the following statement and fact sheet:

The Australian National Council on Drugs:

I. Supports increased access to, and availability of scientifically accepted evidence based treatments for people with drug and alcohol related problems;

II. Supports the trialling and development of innovative treatments for people with drug and alcohol related problems when accompanied by appropriate ethical and evaluation frameworks;

III. Believes it is vital that a comprehensive range of treatments be provided to meet the individual needs and circumstances of people trying to address their drug and alcohol related problems;

IV. Believes that only pharmacological treatments that are registered as safe and efficacious should be available for routine use;

V. Believes that for pharmacological treatments that do not have Therapeutic Goods Administration (TGA) approval, such as sustained release naltrexone preparations, formal registration processes through the approved clinical trial procedures should be followed;

VI. Believes that ongoing use of the TGA Special Access Scheme for sustained release naltrexone preparations circumvents formal processes to ascertain quality, safety and efficacy of pharmacological treatment products and is therefore inappropriate;

VII. Recommends that further independent clinical trials on the safety and efficacy of sustained release naltrexone preparations as a pharmacological treatment for drug dependence be conducted as soon as possible;

VIII. Believes that there needs to be full and informed consent from any clients prior to their engagement in any form of treatment for drug and alcohol dependence and related problems;

IX. Believes that given the very limited Australian data and evidence on the efficacy and safety of sustained release naltrexone preparations, their authorised use through the TGA Special Access Scheme is ethically problematic as it puts patients at risk of unknown harms, for an unknown benefit;

X. Recommends that the TGA and the Department of Health & Ageing resolve the ongoing use of the Special Access Scheme for the use of naltrexone implants and any other sustained release naltrexone preparations that are utilised via this scheme.

Fact Sheet:

- Naltrexone is an opiate antagonist which blocks opioid receptors, and as a result people on naltrexone who take opioids, such as heroin, are unlikely to experience the effects of those opioids;
- Oral naltrexone tablets were approved for prescription use for relapse prevention in opioid dependence in Australia in 1998;
- The effectiveness of oral naltrexone among opiate users is significantly reduced by non-compliance, as people are able to stop taking their tablets to regain the effects of any opioid use;
- In response to this non-compliance, longer-acting, sustained release injectable naltrexone and naltrexone implants have been developed in a number of countries, including Australia;
- A naltrexone implant is a surgically implanted device that provides a slow release of naltrexone over a period of time, effective for 3-6 months;
- Injectible sustained release naltrexone, which is effective for 4 weeks, was approved for the treatment of opioid dependence in the USA in October 2010;
- Previous studies on oral naltrexone have reported increases in the risk of overdose post treatment due to a decreased tolerance for opioids;
- Research regarding whether naltrexone implants and other sustained release preparations can lead to the same risk of overdose or other problems related to their surgical insertion is unclear;
- Despite the strong theoretical background for naltrexone implants, evidence for their safety and efficacy sufficient for registration in Australia has not been presented;
- Despite this lack of Therapeutic Good Administration (TGA) approval for use in humans, naltrexone implants have been inserted in thousands of people in Australia over the last decade;
- Clinicians have been able to obtain and utilise the implants under the TGA Special Access Scheme (SAS), which allows the use of unapproved therapeutic goods for people for whom death is otherwise likely.

Further information:

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NHMRC (2010). *Naltrexone implant treatment for opioid dependence: Literature review*. Available at http:/www.nhmrc.gov.au/your-health/naltrexone-implants.

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