



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;
- Injectable 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 Goods 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:

Bell J, J Kimber, et al. (2003). *Clinical Guidelines and Procedures for the Use of Naltrexone in the Management of Opioid Dependence*. Australian Government Department of Health and Ageing, Publications Production Unit.

Lobmaier P, H Korner, et al. (2008). "Sustained-Release Naltrexone For Opioid Dependence." *Cochrane Database of Systematic Reviews* 2008 (3).

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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