

Response ID ANON-X4HV-75UM-R

Submitted to **Draft Terms of Reference for the Post-market Review of Opiate Dependence Treatment Program Medicines**

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Introduction

1 Which best describes you?

I am responding on behalf of an organisation/institution

2 What is your name?

Name_Indiv:

Claire Celia

3 What is the name of your organisation?

Name_Org:

Australasian Chapter of Addiction Medicine of The Royal Australasian College of Physicians

4 Can we publish your response?

Yes

5 What is your email address?

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6 Would you like to be contacted if there are follow up questions?

Yes

Draft Terms of Reference One

1 Describe and compare essential elements of models of service delivery for opioid dependence treatment (ODT) in Australia (and internationally) including best practice guidelines and current models that support access to ODT medicines through both pharmacy and non-pharmacy settings

ToR-1:

The terms pharmacy and non-pharmacy should be further expanded – ODT treatments (including depot and sublingual buprenorphine and methadone) can be dispensed or administered in a range of settings including community and hospital pharmacies, public and private clinics, outpatient medical practices (GP or specialist), Aboriginal community controlled health services, and correctional facilities.

The differences across these settings are significant, including a range of clinical resources, funding models and patient co-payment, and should be further explored in this review as they impact on the delivery of the opiate treatment program. The TOR needs to ensure that the breadth of clinical practice settings for ODT dispensing / administration is included.

The review also needs to consider emerging models of care that have arisen in response to COVID pandemic*(see note) which has led to many services changing their model of care (e.g. much greater role for unsupervised SL buprenorphine treatment, and increased uptake of depot buprenorphine). Many of these new treatment models may not be reflected in historical guidelines documents in Australia.

* Note: For further information, please refer to this document endorsed by the RACP: Prof Nicholas Lintzeris FACHAM, Dr Vicki Hayes FAFPHM FACHAM, Dr Shalini Arunogiri FRANCP (21 April 2020), Interim Guidance for the Delivery of Medication Assisted Treatment of Opioid Dependence in Response to COVID-19: A National Response. Available online:

<https://www.racp.edu.au/docs/default-source/news-and-events/covid-19/interim-guidance-delivery-of-medication-assisted-treatment-of-opioid-dependence-covid-19.pdf?sfvrsn=1>

Draft Terms of Reference Two

2 Examine the consumer experience, focusing on equity of access and affordability of ODT medicines across the different models of delivery. This will include consideration of access to ODT for at risk population groups including people living in rural and remote areas and Aboriginal and Torres Strait Islander peoples

ToR-2:

Consumer experience is very important and warrants a clear focus in the review.

Aboriginal and Torres Strait Islander peoples represent approximately 10% of clients receiving pharmacotherapy treatment. (Reference: Australian Institute of Health and Welfare 2021. National Opioid Pharmacotherapy Statistics Annual Data collection. Cat. no. PHE 266. Canberra: AIHW. Viewed 07 April 2021, <https://www.aihw.gov.au/reports/alcohol-other-drug-treatment-services/national-opioidpharmacotherapy-statistics>)

In addition to rural and remote, and Aboriginal and Torres Strait Islander peoples, the review should also focus upon key at-risk populations, including:

- People being released from/going into custody –There exists a national under-treatment in custodial settings of people who should be able to access opiate treatment but cannot, with considerable variation across jurisdictions. At present, about 7% of all Australians receiving opiate treatment are in correctional settings and prescribers located in correctional facilities make up about 3.7% of all prescribers. (Reference: Australian Institute of Health and Welfare 2021. National Opioid Pharmacotherapy Statistics Annual Data collection. Cat. no. PHE 266. Canberra: AIHW. Viewed 07 April 2021, <https://www.aihw.gov.au/reports/alcohol-other-drug-treatment-services/national-opioidpharmacotherapy-statistics>)
- People who are homeless or at-risk of homelessness. Housing distress is reported by 10-20% of clients in ODT in many services (Reference: E Black, K Mammen, R Deacon, A Dunlop, M Montebello, D Reid, N Ezard and N Lintzeris. Title: "The MAData Project: Characteristics of clients attending AoD services in 5 Local Health Districts in NSW". Paper presented at Hobart APSAD 2019 National Conference), and impacts upon access to take-away medications and dispensing arrangements (e.g. difficulties in safely storing ODT medications). People who are homeless have identified high levels of substance use and other comorbidities, and experience considerable financial hardship preventing many from being able to afford private ODT.
- People with concomitant chronic pain and opioid dependence. We are seeing increasing numbers of chronic pain patients entering ODT – a trend that is likely to increase with the introduction of real time prescription monitoring. For many such patients, once a day dosing of methadone or SL buprenorphine is NOT optimal treatment for pain management, with many patients requiring split doses (twice a day dosing) - creating difficulties with adherence to current guidelines in many jurisdictions. This clearly impacts upon dosing conditions for such patients. Furthermore, the existing financial conditions of payment for ODT disadvantages them from financial conditions when they previously accessed other prescription opioids (e.g. oxycodone).

In addition to examining consumer voices, we also believe that the TOR should be broadened to include examining and understanding the experience of clinicians working in delivering ODT, including medical practitioners (general practitioners and addiction medicine physicians), pharmacists, and nursing staff. The challenges in providing affordable and sustainable treatment for consumers often requires innovative approaches, but also creates considerable stress for clinicians in this field. It is important that the review understands the issues confronting service providers as well as consumers.

Draft Terms of Reference Three

3 Explore the utilisation of PBS subsidised ODT medicines in Australia, including funding and costs incurred in the supply and dispensing of Opiate Dependence Treatment Program (ODTP) medicines in pharmacy and non-pharmacy settings. This will include examination of current PBS restriction criteria and the impact of the listing of modified release buprenorphine injections on the PBS ODTP

ToR-3:

This aspect should particularly explore unsupervised models of SL buprenorphine–naloxone treatment – as this treatment is the predominant approach internationally (e.g. USA, France), and whilst this has been technically possible in many states across Australia, it has remained under-utilised before the advent of COVID pandemic, where we have seen many services move to unsupervised dosing (e.g. attending a pharmacy once a week, once a fortnight or once a month, with take-away doses on other days). Since COVID, we have seen a marked increase in unsupervised treatment (e.g. >60% SL buprenorphine clients in some services. Reference: Lintzeris N, Deacon R, Hayes V et al. The impact of COVID-19 upon opioid agonist treatment services in south east Sydney, Australia: an evaluation of service changes and patient outcomes. Paper under review Drug and Alcohol Review. 2021) – and this greater emphasis on unsupervised dosing should be considered by the Review moving forward.

Another key area that should be examined is the role of staged supply at pharmacy settings – whereby pharmacists are reimbursed for dispensing high risk medications (e.g. benzodiazepines, prescription opioids) on a daily basis for patients increasing medication adherence and patient safety. However, the opportunity for accessing staged supply with ODT medications has not been possible due to Commonwealth legislation regarding this scheme. Staged supply provides an ideal opportunity to reimburse pharmacists for their labour, without shifting the cost to consumers.

Draft Terms of Reference Four

4 Propose alternative service delivery arrangements for access to ODT medicines, with an aim of identifying an accessible, cost-effective and efficient ODTP for both consumers and the Australian Government

ToR-4:

We support this section of the TOR.

It is particularly relevant to depot buprenorphine and sublingual buprenorphine-naloxone medications, where there are opportunities to consider safe and effective alternative approaches.

Introduction of depot enables doctor and nurse administration without direct involvement of pharmacists. In some instances, pharmacists will also be involved in dispensing, and sometimes in administering depot buprenorphine. At present however, there is no clear model for reimbursement of health professionals. Existing Medicare arrangements for nurse practitioners are not adequate to sustain such a model of care. Similarly, for GPs and addiction medicine physicians, existing Medicare items do not sufficiently reimburse activity and serve as a disincentive for involvement in this treatment approach. There is no payment option for pharmacists at present outside of consumer fees.

The review should consider Staged Supply (instalment dispensing) for ODT medications (methadone and SL buprenorphine products) where treatment involves supervised dosing.

The review should also consider listing SL buprenorphine-naloxone to a S85 medication (instead of a S100 listing) when dosing is not regularly supervised (e.g.,

weekly, fortnightly or 4-weekly dispensing, with a \$6.70 fee for each dispensing occasion) – as occurs with their opioid medications (e.g. Authority prescription for oxycodone or Physeptone medication). An authority prescription approach would increase oversight of the program. The possibility of a joint S85 and S100 listing for SL buprenorphine-naloxone should be considered.

Final comments

Do you have any additional comments or feedback regarding the draft ToR for the ODTP PMR?

Additional:

The review should reflect on the changes arising from COVID, which has led to a greater emphasis on the role for ODT with minimal supervised dispensing – particularly for SL BPN. These changes may not be reflected in existing guidelines that predate COVID. Whilst COVID is likely to not be a long term issue – the experience of moving towards unsupervised models of care (especially for SL BPN) – will result in a greater role for this approach and needs to be reflected in future models of ODT medication arrangements and funding.

The review should also consider the likely impact of introducing real time prescription monitoring programs across Australia. This may lead to an increase in the number of patients in ODT, and an increase in the number being treated with unsupervised dosing models of care.

The review should also examine the likely impact of depot buprenorphine upon the mix of ODT medications being used. Many experts predict that depot buprenorphine products will account for over half of the ODT market within several years. This will almost certainly reduce the cost of funding supervised dosing for a diminishing number of patients in methadone or supervised SL buprenorphine treatment. The treatment landscape is undergoing major changes in Australia, and this is a timely review to establish a sustainable and fair treatment system for this important treatment modality.

Given their relevant knowledge and expertise in ODT, it is essential that experts in addiction medicine be involved in the Post-Market Review of Opiate Dependence Treatment Program Medicines. We therefore strongly recommend the Department of Health seeks representatives from the RACP's Chapter of Addiction Medicine to take part in the review.

Importantly, there are significant inequities of access to ODT in the current system and these need to be addressed urgently. We therefore urge the Department to get the Post-Market Review under way as soon as possible.

Should you require any further information about this submission, please contact Ms Claire Celia, Senior Policy & Advocacy Officer on Claire.Celia@racp.edu.au or Policy@racp.edu.au.