

## HRA Submission

# Public Consultation for the Post-market Review of Opiate Dependence Treatment Program Medicines

1<sup>st</sup> October 2021

**ToR 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 (including models developed in response to the COVID-19 pandemic) that support timely access to ODT medicines through both pharmacy and non-pharmacy settings\*.**

*\*Non-pharmacy settings include a range of service settings where ODT medicines are delivered in Australia including, but not limited to, correctional facilities, hospitals, public and private clinics, Aboriginal Community Controlled Health Organisations, general practices and specialist clinics.*

### **Essential Elements of Ethical & Best Practice Service Models:**

Opioid Dependence Treatment (ODT) is the first-line treatment for people who are dependent on opioids, the medications used are listed as 'Essential Medicines' by the World Health Organisation (WHO) and it is one of the most effective, evidence-based forms of medical treatment available globally. Harm Reduction Australia (HRA) along with many other organisations and individuals, believe that an essential element of an ethical and best practice approach to the timely provision of ODT in the community means taking urgent steps to remove the current financial discrimination being imposed by all governments on a highly marginalised group in the Australian community.

In addition to being an already highly stigmatised and marginalised community, people on the ODT program in community pharmacy settings (and private clinics in NSW) have been left to carry the costs of uncapped and unregulated dispensing fees for decades. These private fees that can equate to up to \$200/month (sometimes more), are both unfair and a significant barrier to treatment access. This inequitable situation has continued unabated despite long-standing advocacy by consumer advocates and multiple coronial inquiries recommending changes to the affordability of access to ODT on the basis that an affordable program might have prevented tragic loss of life. For these reasons, over the past 18 months HRA has renewed its focus on this issue and engaged in a strenuous advocacy campaign seeking urgent changes to the ODT program. In particular, we have raised questions about the current listing arrangements for these medications on the Pharmaceutical Benefits Scheme (PBS) and how changes to these arrangements can remove the discrimination that currently underpins the program and ensure better and more equitable access to the ODT program for all who require it (see ToR 3 & 4 for further detail).

In this context, HRA welcomes specific attention to review the current ODT Program although we would like to note, in the strongest possible terms, at the commencement of this submission that HRA has serious concerns about the need for a lengthy policy review process such as this PMR to resolve the discrimination outlined above. It is our view, that there is already ample evidence in the form of existing research, advocacy and policy reports, to support the need for urgent and immediate action in relation to the key priority area of affordability/cost for those on ODT and other associated barriers to access. While HRA recognises the historical nature of the program and even agrees that the need to review arrangements across the entire ODT program are well overdue, we are also very concerned about the ongoing harms, discrimination and disadvantage that people on the ODT program will be forced to continue enduring while this review process is undertaken.

To this end, we wish to take this opportunity to re-state our strong recommendation (made in our correspondence to Minister Hunt and the PBAC Chair, Prof. Wilson) that, in the absence of immediate action to remedy the dispensing fees issue, there is a need for an immediate moratorium on dispensing fees currently being paid by people on the ODT program at community pharmacies and private clinics until a longer-term solution is found through this PMR process. We also re-state our position that, given the decision has now been taken to conduct this PMR process, it must be conducted as swiftly as possible in the interests of minimising ongoing harms and disadvantage to people on the ODT program due to the current discriminatory arrangements. Further, HRA is concerned that given the wide ranging scope of the Terms of Reference (ToR) for this review process, there is a significant risk of delays and deferrals particularly on matters and demarcations relating to jurisdictional responsibilities (between federal and the states/territories) where reaching consensus and clear outcomes is often difficult. Attention to avoiding the negative outcomes outlined above should be a priority for those overseeing the PMR process.

### ***Other Comments on Existing Service Models (Aus & International):***

With the above foundational principles in mind, our remaining comments on ToR 1 relate to specific points HRA would like to make on existing models of service delivery for ODT both within Australia and internationally as well as some key considerations in relation to the COVID-19 pandemic. As noted above, the ODT program has been in existence in Australia for over 5 decades. Across this time, periodically we have seen some additional resourcing provided for medications at the federal level, along with structural changes at the state/territory level that have largely focused on improving the administration of a growing program from a governmental perspective. Despite these medication funding and administrative developments, few would argue with the observation that the ODT program in Australia (particularly from the perspective of those on the program) has been chronically neglected.

This was underscored by comments, on the public record, made by Departmental officials at Senate Estimates in October 2020 that clearly indicate a generalised lack of understanding about how people are getting access to and affording ODT medications (that is, medications that are PBS listed and federally funded). Further comments by Departmental officials in Senates Estimates in March 2021 suggest that the lack of clarity and understanding about matters of access and equity in relation to the ODT program, are due to the length of time the program has been in place and that, that the current discriminatory arrangements have innocently evolved as the program has moved from one administered in state/territory-run 'clinics' (whereby treatment was provided without charge to all) to a more diversified model where some people now access their medication via community pharmacy.

The problem with the above-mentioned Departmental comments is three-fold: first, the ODT program has not just evolved recently into this 'hybrid model'. While it varies across jurisdictions, people have been accessing the ODT program through community pharmacy since at least the 1980s, with a majority of people dispensed in community pharmacy for well over a decade (most recent NOPSAD data states 75% of people on ODT are dispensed in community pharmacy). Second, ODT advocates have been raising serious concerns about the impact of private dispensing fees for over two decades with little or no response from federal or state/territory governments (see below for discussion of one partial exception in the ACT). Thirdly and as noted above, even before the most recent round of advocacy drawing attention once again to the current discriminatory arrangements, there have been multiple coronial inquiries specifically recommending the need to address this issue as a matter of urgency. In short, this is not 'news', not to the Department, nor to the states/territories or to anyone who works with or is involved in the ODT program - it is therefore, disingenuous at best, for anyone to suggest it is.

As a result, the amount people on the ODT program are forced to pay to access their medications has been left to run largely unchecked along with many other access and equity concerns related to the overtly punitive and paternalistic models of service delivery favoured at the jurisdictional level. There are unfortunately very few examples where concrete and enduring steps have been taken by jurisdictional governments to address access and affordability issues for those on ODT in community pharmacy. One exception that is frequently presented as both a positive example and possible solution is that of the ACT.

The subsidisation model favoured by the ACT Government whereby people on ODT pay (direct to the pharmacy) a set fee of approx. \$15/week with the ACT Government subsidising a further approx. \$25/\$30/week/service user direct to the pharmacy allows for a service model that caps the 'consumer co-payment' at a 'more affordable' level and ensures the pharmacist is adequately remunerated. Despite these 'steps forward', HRA would argue that the fundamental problem with the ACT subsidisation approach is that it does not in any way address the inherent discrimination at the heart of the current service model/listing arrangement for ODT medications. People on the ODT program at community pharmacy in the ACT might pay a little less each week to access their medications, but the arrangement still means that they are paying considerably more than other Australians to access their PBS listed medication and these payments do not count toward their safety net - these 'co-payment' and 'safety net' issues can have significant implications for the majority of people on ODT who are living on fixed low incomes (incl. government benefits) and/or are living with multiple chronic conditions.

To HRA's knowledge, there is no comprehensive overview of ODT service delivery models in countries other than Australia. Having said this, of the information that is available, there appear to be few examples of highly innovative approaches (that do not rely on punitive and paternalistic models) although various countries have or have had low-threshold, mobile, outreach and community-based service models aimed at improving access and lowering barriers. There are some examples also of peer support models whereby people with direct lived experience of ODT undertake certain key roles including reception, triaging, in-reach/outreach, dispensing medications, counselling and support, information and referral and other roles to create more acceptable and accessible service models. Often again, documentation and evaluations of these innovative service approaches can be difficult to find largely due to under-resourcing where available funding goes to service provision rather than evaluation and write-up. Nevertheless, HRA can provide further details on existing documentation where it is available, should these approaches be of further interest to the PMR. Finally, in relation to the specific issue of affordability/cost a noteworthy example in our region is Aotearoa/New Zealand and their approach to funding ODT. While Aotearoa/New Zealand has various arrangements for how people on ODT pay for their prescription/GP consultation fees depending on their circumstances, everyone on the ODT program at community pharmacy is able to access their ODT medications free of charge (regardless of circumstances). This has been made possible in part, because of their system of national government that has allowed for a single standardised arrangement across the entire country. This highlights the importance federal government leadership in the resolution of these chronic problem with the accessibility and affordability of ODT medications in Australia so as to facilitate a clear, equitable and sustainable arrangement for all Australians regardless of whether they live in rural, regional or metropolitan areas.

### ***COVID-19 Pandemic:***

In relation to service model changes and/or developments in response to COVID-19 pandemic. While the results of studies into the impacts and outcomes of the COVID-19 pandemic for people on the ODT program are still emerging (and mostly relate to specific geographical areas/health districts), there are a range of overview comments that HRA would like to make in relation to the COVID-19 pandemic and ODT.

These comments are informed by the available and emerging research and direct living experience. First, is that although there were some changes in the form of more flexible arrangements particularly in the first nation-wide COVID lockdown i.e. longer prescription periods, more tele-health appointments for script renewals and other ODT matters, expanded levels of take-away or take-home doses, less face-to-face attendance at the pharmacy or clinic (including pushing people to local pharmacies for dosing instead of large public clinics), allowing third-party collection, providing home-delivery of take-away doses for exceptional reasons and expanded access to long-acting injectable buprenorphine (LAIB), these 'flexibilities' warrant further discussion. Specifically, despite high levels of nervousness and concerns about potential risks, there have been few if any adverse outcomes from making the program more flexible. Indeed, the evidence indicates that there were many positive outcomes for those who had access to such measures.

Unfortunately, there are increasing reports that these changes were not made as available as they could or should have been under the circumstances and, that the level of availability has been over-stated. This meant that people continued to be put at unnecessary risk of COVID infection due to misplaced (but entrenched) fears of opening the ODT program to greater flexibilities. However, we are unaware of any reported increases in the rate of overdose associated with greater ODT flexibilities, nor any problems with greater diversion or increases in injecting related harms or injuries. Our conclusion is that it simply made life more flexible and manageable for people.

Although the majority of the COVID policy flexibilities implemented in relation to ODT were considered to have positive outcomes, where there were negative impacts, once again they related to cost and affordability issues. For those who were 'pushed out' to local pharmacies for dosing instead of coming into potentially large crowded public clinics on a daily basis, there have been some reports of problems with the cost of dosing and disagreements between pharmacists and people on the program. We raise this issue because it highlights again how cost and affordability in the pharmacy context, remains as a major barrier even to broader policy and service model changes that ultimately could make the ODT program a less stigmatising and restrictive experience by allow people to pick-up their medication at community pharmacy rather than being at a large public clinic simply because they cannot afford a pharmacy closer to home.

Despite the many positive outcomes outlined above, people on the ODT program are complaining that these arrangements, for the most part, have not been sustained following the first COVID lockdown and that far fewer flexibilities have been made available in subsequent/current COVID lockdowns. There has however been what some people on ODT (and others including GPs) are describing as an inappropriate 'push' to initiate people onto the LAIB medications over other currently listed ODT medications during the COVID-19 pandemic. While it is difficult to know at this point whether this is about a greater focus on a new medication or, has developed as a direct result of COVID-19 policies to reduce contact with clinics and providers, HRA believes this issue needs ongoing monitoring. While HRA strongly supports more ODT medication options being made available to people who require ODT (including LAIB for those who want it), we strongly believe that these options always need to be made available in addition to current options and in a way that is based fully on genuine choice and informed consent.

This must include greater scrutiny of cost issues associated with the dispensing of these new medications as HRA is already aware of claims that some pharmacies are charging even higher amounts (than what is typically charged for other ODT medications) for access to LAIBs.

Finally, it is clear the recent advocacy (as highlighted above) and other issues including COVID-19 pandemic have created some momentum for much-needed reform in the ODT program. This is not surprising given the model upon which the ODT program is delivered is no longer fit for purpose given all the significant developments over the past 30 years or more. The inherent discrimination in the current ODT Program not only places inexplicable barriers to treatment but also highlights a neglect of the ODT Program that has endured across many governments for far too long. HRA nonetheless remains committed to working collaboratively with governments and all stakeholders to help address these longstanding issues with Australia's ODT program and will continue with our efforts until reforms are achieved.

**ToR 2. Examine the consumer experience, focussing on equity of access, geographical barriers to access, cultural safety, and affordability of ODT medicines across the different models of service delivery. This will include consideration of access to ODT for at risk population groups including people living in rural and remote areas, Aboriginal and Torres Strait Islander peoples and other populations who may have limited access to health care services, including ODT.**

Although in response to ToR 1 above we have outlined what we believe is one of the key barriers to equity of access and affordability for majority of people on the ODT program (that is, the over 75% of people currently dispensed in community pharmacy and private clinic settings), there are a few additional comments that relate to the experience of ODT service users we wish to make. These comments specifically relate to issues of stigma and discrimination, geographical barriers, cultural safety and issues for people in immediate post-release from prison.

Thus far we have focused on the urgent need to resolve the current discriminatory arrangements in relation to uncapped and unregulated dispensing fees that HRA argues violate the legal right of people on ODT under Federal Disability Discrimination law (see: Disability Discrimination Act 1992 (Cth) (DAA) (Marsden v HREOC [2000] FCA 1619) not to be treated differently on the basis of their opioid dependence. Currently, people on ODT are required to pay private dispensing fees that other Australians accessing PBS listed medications are not required to pay and furthermore, these fees do not count toward their PBS Safety Net (as they do for other Australians). HRA further argues that these exclusions are applied exclusively to people on the ODT program and therefore, treat people on ODT less favourably than other Australians purely on the basis of their opioid dependence. These discriminatory arrangements need to be redressed immediately.

Beyond this specific discriminatory situation at law, HRA also believes it is important to highlight ongoing concerns about the broader effects of stigmatising attitudes and associated discriminatory actions on the lives and health of people on the ODT program. The level and extent of stigma and discrimination experienced by people on ODT (and people who use alcohol and other drugs more broadly) is well-documented. There is plethora of research studies, reports, papers and commentaries detailing the systemic and entrenched nature of stigma and discrimination with AOD services and Australian society more broadly. These publications also document the extent of the harms, violence and rights violations that are routinely perpetrated under the guise of these harmful and damaging attitudes and values. Indeed, experiences of stigma are so pervasive for people who use/have used drugs, that stigmatising experiences are said to be an almost universal and daily experience for this group in the community. There are no quick and easy answers that can be provided in the context of this brief submission to effectively address this widespread and entrenched problem for the AOD sector.

Nonetheless, HRA believes it is critical at this early point in the PMR process to stress the importance of ensuring that the current pervasive problems associated with stigma and discrimination in the ODT program context (and their effects) are not 'swept under the carpet' or minimised across this process. Rather, we would argue that issues of stigma and discrimination need to be 'front of mind' and considered as integral to all considerations and solutions undertaken and proposed by this PMR. Without this level of transparency and commitment, HRA believes that stigma and discrimination will continue to undermine other strategies aimed at improving the equitable, timely, reliable and affordable access to ODT medications for people on the program.

The chronic problems with cost and affordability outlined in ToR 1 above and the proposals HRA have outlined to address these below will significantly benefit those in rural and remote areas including Aboriginal and Torres Strait Islander people. For people living in these communities, pharmacy is often the only the option for accessing ODT with public ODT clinics being located almost exclusively in larger regional and metropolitan areas (if they exist at all). Even where public clinics do exist in regional areas (and metropolitan areas for that matter) they rarely have an additional capacity to take on new ODT service users. Again, this is in large part due to the cost of dispensing fees in community pharmacy which make it prohibitive for people to move from the public clinic into a GP/community pharmacy arrangement once they are settled on the program and therefore, places in public clinics are rarely 'freed-up'.

For the most part, regional and especially rural areas do not have public clinics (or even private clinics) and therefore pharmacy may be the only option and that pharmacy may not be in the same town or regional city. This can mean that in addition to having to pay large ODT dispensing fees (that are uncapped and unregulated so they can change at any time), people on ODT in these areas sometimes must cover significant travel costs to and from the pharmacy whenever they are required by their prescription to do so. This means, that in addition to all of the above, it is very important that these ODT service users do not get behind or default on ODT dispensing fees because any breakdown in relationship can not only risk the therapeutic relationship with the pharmacist concerned, but their access to treatment more broadly as it may be the only ODT Program option in the area or for some distance.

This of course, also raises important issues about privacy and confidentiality associated with being on an ODT program in a small town or community. This can be very important for people in relation to family and culture, but also again, highlights the benefits of greater flexibility so that people are not having to potentially expose themselves when going to and from the pharmacy every day or multiple times a week. There are many accounts of people losing employment, housing, enduring family breakdown and even having their children removed due to being 'seen' regularly at a pharmacy and 'found' to be on an ODT Program.

HRA does not in any way claim to speak for Aboriginal and Torres Strait Islander people or communities. We do wish to take this opportunity to fully support calls by Aboriginal and Torres Strait Islander communities for culturally safe ODT service models to be properly resourced and made available in ways that attend to the specific needs and circumstances of Aboriginal and Torres Strait Islander people who require the ODT program. Aboriginal and Torres Strait Islander people should also be appropriately represented and consulted across, within and through all aspects of the PMR process.

Finally, in relation to this ToR, HRA would like to draw attention to the under-discussed and under-addressed issues for people on the ODT program who are recently post-release from prison or youth detention. Too often this group of people are “out of sight out of mind” and it means they are left highly vulnerable to preventable harms and death particularly from accidental overdose. We raise these concerns in the context of open acknowledgements of an increase in the prescribing of the new LAIB medications in prisons (particularly in NSW) also referred to in the most recent NOPSAD data. While it is well acknowledged that this new form treatment is favoured from a prison administration perspective, what is less acknowledge or even discussed, are the additional responsibilities the increased use of this new form of medication brings with it to ensure that those who are initiated onto these long-acting depot-based medications in prison, are adequately supported when leaving and post-release.

Adequate support means not only making sure people are fully informed and consenting to this treatment when it is prescribed for them, but are made aware of what they need to do once they leave prison including how to find a new prescriber for a medication that is not yet fully available in the broader community, when they should start the process of doing this, what to do if they can't access another LAIB prescriber, and of course once again, what costs could be involved. Prison post-release is a notoriously difficult area of health and social services delivery and although it should not have to, ODT inevitably further complicates this picture significantly for people at a highly vulnerable time. HRA advocates therefore that greater attention needs to be paid to the full spectrum of ODT program issues for people post-release from prison, not just LAIBs but all ODT medications and how these relate to people's wider post-release needs and circumstances (including whether people wish to continue on LAIB once released from prison, that is, a form of treatment that suits their needs in prison may not suit their needs post-release). Given the unacceptable over-representation of Aboriginal and Torres Strait Islander people in Australian prisons and youth detention, this also links to the statements above in relation to the provision of culturally safe ODT services for Aboriginal and Torres Strait Islander people and communities.



**ToR 3. Explore the utilisation of PBS ODT medicines in Australia, including funding, benefits (health system and societal) 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 listing of modified release buprenorphine injections on the PBS ODTP.**

The latest NOPSAD data (2021) shows that the ODT Program is a significant public health initiative with over 53,000 people currently on the program with a majority of people on methadone (58%), followed by buprenorphine/buprenorphine-naloxone (42%) (in all its formulations including 2% LAIB). When the size of the ODT Program is taken together with the considerable scientific literature supporting the safety, efficacy and cost-effectiveness of these medications over many decades, it is abundantly clear that ODT has enormous health and social benefits (directly and indirectly) for the entire Australian community. The latest NOPSAD data also identifies that the program has grown at the rate of approx. 5% since 2019. Given that most of this growth rate is thought to be associated with the newly available LAIB medications (particularly in NSW), HRA believes this review provides a critical opportunity to find a sustainable solution to the long-standing problems of access and affordability already outlined above.

Although HRA fully acknowledges and supports the funding provided by the Federal Government for the ODT medications themselves (and that this funding has increased as the program has grown in size), funding for the medications does not address the above problems associated with the uncapped and unregulated dispensing fees for the majority of people dispensed in community pharmacy. Under the current s100 PBS listing arrangements, people on ODT can and do pay widely varying amounts for their medications to be dispensed in the community pharmacy setting from \$50/month to over \$250/month.

Having said this, most people are likely to be paying upwards of \$140/month and as already stated above, a majority of people on the ODT Program are dispensed in community pharmacy settings, so it is a significant issue that requires resolution. In addition to variation in how much is paid by people on the program each month, there is also a great deal of variety in how individual pharmacists approach these uncapped and unregulated fees. For example, some people are required to pay daily for every dose, others pay even if they miss a dose/aren't dispensed, some charge extra to dispense take-home doses, some charge a fee for the cost of the plastic bottle for take-home doses, others will not dispense a take-home dose unless people on the program are paid up-to-date or even in advance, some charge a weekly or fortnightly fee regardless of the circumstances.

HRA also acknowledges that some pharmacists do what they can to manage the costs of ODT dispensing by dosing people even if they can't pay and/or allowing debts to build that people may or may not be in the position to repay. Clearly, the current system is complex and wide ranging in its application, and this causes incredible hardship and distress for many people on the ODT Program and unnecessary stress for many pharmacists.

It is important to highlight here, that this is a clinical program that should be based on a therapeutic NOT financial relationship. Unfortunately, the current system not only forces the pharmacist into the role of debt collector and out of any possibility of a therapeutic relationship, but people on the program are often forced to be focused on many other issues unrelated to their therapeutic goals. For example, research into the negative effects of these uncapped and unregulated dispensing fees show that people regularly go without their medication because they cannot afford it. Furthermore, they also go without food just to pay for their daily medication, a medication, which to restate, is listed as an 'essential medicine' by the WHO. In addition, people on ODT Programs have discussed their distress at their children going without essentials due to them having to pay for dispensing fees and being forced to make money (however they can) to obtain their PBS listed medication.

As noted above, HRA acknowledges the important role of the Federal Government in funding the ODT medications through the PBS. However, as stated previously, this funding is far from adequate in securing the equitable, timely, reliable and affordable access to these medications for the majority of people on the ODT Program in 2021 in Australia. Of course, it is possible for the Federal Government to 'wash their policy hands' of further responsibility for access to these PBS listed medications on the basis that "administration for the program rests with the states and territories". Regardless of whether this statement is accurate or not in a policy and legislative sense, HRA believes that there are more important issues at stake here. These issues include asking ourselves how is it that some of the most marginalised people in the Australian community are constantly struggling to get equitable, timely, reliable and affordable access to PBS listed medications they require?

It also includes, explaining to families and communities why access to a proven treatment has so many barriers given the significant health, social and economic harms associated with untreated opioid dependence. HRA would suggest that these issues raise some important ethical questions for this PMR process to consider.

While HRA will not list all of them here, one of the most important issues that needs to be foregrounded in considering how to address the issues raised across this submission, is how to address these critical issues without creating a two-tiered system. What do we mean by this? First and foremost, it is about equity - not forcing people on to a particular medication simply because it is more affordable rather than what is clinically indicated and best suits their particular situation. This means that all ODT medications should be listed and made available in such a way that regardless of the medication, people pay the same cost, that is, what any other Australian would pay to access a PBS listed medication in accordance with the latest PBS Patient Co-payment and Safety Net Thresholds. If this entails making further specific payments available to community pharmacists to ensure they are fairly and appropriately remunerated for their time and expertise, then this should be part of shaping a new approach to addressing these issues.

**ToR 4. Propose improved service delivery arrangements for access to ODT medicines, with an aim of identifying an ODTP that is equitable, timely, reliable and affordable for consumers and stakeholders involved in the supply and delivery of ODT medicines and cost-effective for the Australia Government.**

While HRA fully acknowledges that there is much that can be improved in the ODT Program, it is our view that the most pressing issue facing those on the ODT program is cost and the current discriminatory arrangements that are creating a multitude of barriers to equitable, timely, reliable and affordable access to ODT medications. One of HRA's greatest concerns in this PMR process is the potential for this issue to be pushed back and forth between the Federal Government and State/Territory Governments. HRA has observed this result far too often, and on this occasion, there is a need for a proper, long-term and sustainable solution and it needs to be immediately implemented - not in some possible distance future when (and if) other factors 'magically align'.

In this regard, from HRA's perspective it is critical for this review not to get side-tracked on myriad other issues associated with the ODT Program. While it is enormously important to acknowledge there are so many issues to address in this decades old program that have never been properly reviewed and updated, the PMR should not be allowed to result in anything less than clear, actionable, timely and ethical outcomes. This means immediately addressing the current discriminatory arrangements in relation to the uncapped and unregulated dispensing fees being charged every day, of every week, to people on the ODT Program while this PMR process takes its course. Once this urgent human rights issue has been adequately and properly addressed, then other issues within scope of review should be comprehensively taken up and recommendations made. Nonetheless, cost is an issue that is firmly within the scope and remit of PBAC and can be fixed right now and therefore, HRA restates its previous recommendation:

*That HRA notes statements by the Minister for Health, the Hon Greg Hunt MP, that he is legally obliged to accept the recommendations and related advice of the Pharmaceutical Benefits Advisory Committee (PBAC). Accordingly, HRA is requesting the PBAC make a recommendation to the Government to dual-list buprenorphine, buprenorphine + naloxone and methadone under s85 and s100 of the PBS. This will allow people on the ODT program to have access to the same patient co-payment and safety net arrangements that all other Australians have for PBS listed medications they require.*

Despite our concerns with the lack of any real or substantive change in the ODT Program to reflect the changes over the past 30 years or more, we remain committed to working collaboratively with governments and all stakeholders to help address these longstanding issues with Australia's ODT Program and will continue with our efforts until reforms are achieved. Thank you again for the opportunity to provide input into this important process.