



14 April 2021

The Hon Greg Hunt MP  
Minister for Health and Aged Care  
Parliament House  
CANBERRA ACT 2600

Via email: [Minister.Hunt.DLO@health.gov.au](mailto:Minister.Hunt.DLO@health.gov.au)

Dear Minister,

**Status of the special arrangement for the Opiate Dependency Treatment program**

I am writing, on behalf of the Senate Standing Committee for the Scrutiny of Delegated Legislation (the committee) in relation to the status of the special arrangement for the Opiate Dependency Treatment (ODT) program made under section 100 of the *National Health Act 1953* (the Act).

On 8 March 2021, the committee received correspondence from Better Access Australia in relation to this matter, in which Better Access Australia has suggested that the special arrangement for the ODT program has been inappropriately made as a non-legislative instrument. Better Access Australia also notes that other special arrangements made under section 100 of the Act have been registered as legislative instruments on the Federal Register of Legislation. Please see attached a copy of the correspondence from Better Access Australia.

In addition, the committee is aware of evidence given by Department of Health officials at a Senate Estimates hearing on 24 March 2021; during which officials explained that work to create a legislative instrument for the ODT program has commenced.

Noting that the committee is strictly concerned with matters relating to the technical scrutiny of delegated legislation, the committee has resolved to write to you to seek your advice in relation to the status of the special arrangement for the ODT program. As a legislative scrutiny committee, the committee does not form a view in relation to the policy intention underpinning the special arrangement.

**The committee requests your advice as to why the special arrangement for the ODT program made under section 100 of the *National Health Act 1953* was made as a non-legislative instrument; and further, why the department has undertaken to create a legislative instrument for the ODT program.**

To facilitate the committee's timely consideration of the matters above, the committee would appreciate your response by 30 April 2021.

If you have any questions or concerns, please contact the committee's secretariat on (02) 6277 3066, or by email to [sdlc.sen@aph.gov.au](mailto:sdlc.sen@aph.gov.au).

Thank you for your assistance with this matter.

Yours sincerely,

**Senator the Hon Concetta Fierravanti-Wells**

**Chair**

**Senate Standing Committee for the Scrutiny of Delegated Legislation**



**The Hon Greg Hunt MP**  
**Minister for Health and Aged Care**

RefNo: MC21-011145

Senator the Hon Concetta Fierravanti-Wells  
Chair  
Senate Standing Committee for the Scrutiny of Delegated Legislation  
Parliament House  
CANBERRA ACT 2600

10 MAY 2021

Dear Chair

*Concetta*

I refer to your correspondence of 14 April 2021 concerning the status of the special arrangement for the Opiate Dependence Treatment Program (ODTP) made under section 100 of the *National Health Act 1953* (Act).

The ODTP operates for the benefit of people with opioid dependency by supporting access to medicines to treat that dependency through a variety of state and territory managed dosing point sites in pharmacy and non-pharmacy settings, such as health clinics, non-government organisations, medical centres and other state managed facilities. The ODTP is being administered by the Commonwealth within existing legal authority. It is not unlawful. Section 100 of the Act provides the legislative authority for the Commonwealth to make direct payments to pharmaceutical companies for supplies of medicines listed on the ODTP.

Following a freedom of information request in July 2019, my Department released the ODTP special arrangement to the enquirer and made a commitment to the Office of the Australian Information Commissioner to progress work in 2020 to register a special arrangement for the ODTP. My Department consulted with key stakeholders on a draft legislative instrument for the ODTP from 30 November 2020 to 18 December 2020.

Through the consultation process for the special arrangement, stakeholders raised significant concerns about current administration arrangements for state and territory governed opioid dependence treatment programs and access to medicines for opioid dependence. The administration arrangements will need to be considered by my Department directly with jurisdictions and also through the recently announced Post-market Review (PMR) of the ODTP led by the independent Pharmaceutical Benefits Advisory Committee (PBAC). The Australian Government relies on expert advice of the PBAC in matters related to the Pharmaceutical Benefits Scheme. I expect the PBAC to complete the review within 12 months. It is anticipated that any program changes arising from recommendations of the PMR would likely require amendments to the special arrangement, hence it is prudent the outcomes of the PMR be considered prior to registration of a legislative instrument.

Thank you for writing on this matter.

Yours sincerely,

Greg Hunt



17 June 2021

The Hon Greg Hunt MP  
Minister for Health and Aged Care  
Parliament House  
CANBERRA ACT 2600

Via email: [Minister.Hunt.DLO@health.gov.au](mailto:Minister.Hunt.DLO@health.gov.au)

  
Dear Minister,

### **Status of the special arrangement for the Opiate Dependency Treatment program**

Thank you for your letter to the Senate Standing Committee for the Scrutiny of Delegated Legislation (the committee) dated 10 May 2021 in relation to the status of the special arrangement for the Opiate Dependency Treatment (ODT) program made under section 100 of the *National Health Act 1953* (the Act).

The committee notes your advice that the ODT program supports access to medicines for people with opioid dependency, and that the program is run in through state and territory managed dosing point sites.

The committee also notes your advice that the ODT program is being administered by the Commonwealth within existing legal authority.

Further, the committee notes that the commitment to register a new special arrangement for the ODT program was made following a freedom of information request in July 2019; and that through the consultation process for the new special arrangement, stakeholders have raised significant concerns about current administration arrangements for state and territory governed opioid dependence treatment programs and access to medicines for opioid dependence.

It remains unclear to the committee, however, whether the current special arrangement for the ODT program should be a legislative instrument, noting that it may be legislative in character.

In order to further clarify this matter, the committee would appreciate your advice as to why it is considered that the current special arrangement for the ODT program is not legislative in character and therefore not subject to the requirements of the *Legislation Act 2003*, including disallowance and scrutiny by the committee under standing order 23.

To facilitate the committee's timely consideration of the matters above, the committee would appreciate your response by 7 July 2021.

If you have any questions or concerns, please contact the committee's secretariat on (02) 6277 3066, or by email to [sdlc.sen@aph.gov.au](mailto:sdlc.sen@aph.gov.au).

Thank you for your continued assistance with this matter.

Yours sincerely,

**Senator the Hon Concetta Fierravanti-Wells**

**Chair**

**Senate Standing Committee for the Scrutiny of Delegated Legislation**



**The Hon Greg Hunt MP  
Minister for Health and Aged Care**

Ref No: MC21-018822

08 JUL 2021

Senator the Hon Concetta Fierravanti-Wells  
Chair  
Senate Standing Committee for the Scrutiny of Delegated Legislation  
Parliament House  
CANBERRA ACT 2600

Dear Chair

*Connie*

I refer to your further correspondence of 17 June 2021 concerning the status of the special arrangement for the Opiate Dependence Treatment Program (ODTP) made under section 100 of the *National Health Act 1953*.

In my letter from 10 May 2021, I advised my Department is progressing work to address the historical registration issue and register a special arrangement for the ODTP as soon as is practicable. However, the ODTP has been in place for several decades across multiple governments and significant concerns about the administration arrangements for opioid dependence treatment, governed by the states and territories, have been raised by stakeholders, including consumer advocacy groups. It appears these will need to be considered through the Post-market Review of ODTP medicines (Review) and directly with jurisdictions before the instrument can proceed.

I anticipate that any changes to the ODTP that may arise from recommendations made by the Pharmaceutical Benefits Advisory Committee following the completion of the Review will likely need to be reflected in the special arrangement, and as such it is important that the Australian Government take this into account prior to registration of a legislative instrument.

I would like to assure the Senate Standing Committee for Scrutiny of Delegated Legislation that the ODTP will continue to operate under the existing special arrangement until an instrument that reflects the outcome of the Review can be registered.

Thank you for writing on this matter.

Yours sincerely

Greg Hunt



16 August 2021

The Hon Greg Hunt MP  
Minister for Health and Aged Care  
Parliament House  
CANBERRA ACT 2600

Via email: [Minister.Hunt.DLO@health.gov.au](mailto:Minister.Hunt.DLO@health.gov.au)



Dear Minister,

### **Status of the special arrangement for the Opiate Dependency Treatment program**

Thank you for your letter to the Senate Standing Committee for the Scrutiny of Delegated Legislation (the committee) dated 8 July 2021 in relation to the status of the special arrangement for the Opiate Dependency Treatment (ODT) program made under section 100 of the *National Health Act 1953* (the Act).

The committee notes your advice that your department is currently progressing work to address the historical registration issue and register a special arrangement for the ODT program as soon as is practicable.

The committee also notes your advice that the Post-market Review of ODTP medicines (Review) will inform this process and that you anticipate that any changes to the ODT program which may arise from recommendations made by the Pharmaceutical Benefits Advisory Committee following the completion of the Review will likely need to be reflected in the special arrangement.

While the committee welcomes this advice, it remains unclear whether the current special arrangement for the ODT program should be a legislative instrument.

It appears to the committee that the ODT program special arrangement may be legislative in character, noting that, as set out in subsection 8(4) of the *Legislation Act 2003*, it appears to determine the law, and has the direct or indirect effect of affecting a privilege or interest, imposing an obligation, creating a right, or varying or removing an obligation or right.

The committee notes that other special arrangements made under section 100 of the Act are recognised as being legislative in character, and therefore registered as legislative instruments, and it appears this status may apply equally to the ODT program special arrangement.

The committee further notes that, as set out in section 15K of the *Legislation Act*, a legislative instrument is not enforceable by or against any person (including the Commonwealth) unless the instrument is registered as a legislative instrument.

In this context, the committee notes that a challenge to the validity of the current special arrangement on the basis that it should have been registered as a legislative instrument may result in a court finding the actions undertaken under the current arrangement to be unlawful.

Finally, the committee notes your advice that the ODT program will continue to operate under the existing special arrangement until a legislative instrument that reflects the outcome of the Review can be registered.

I take this opportunity to advise that, in accordance with its regular scrutiny of instruments, the committee will closely examine the new special arrangement for the ODT program after it is registered on the Federal Register of Legislation.

If you have any questions or concerns, please contact the committee's secretariat on (02) 6277 3066, or by email to [sdlc.sen@aph.gov.au](mailto:sdlc.sen@aph.gov.au).

Thank you again for your assistance with this matter.

Yours sincerely,

**Senator the Hon Concetta Fierravanti-Wells**  
**Chair**  
**Senate Standing Committee for the Scrutiny of Delegated Legislation**