

s38

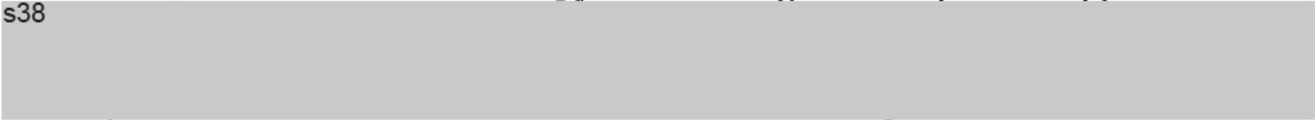
Evidence taken into account

18. In considering the exercise of my discretion and making my decision, I took into account the contents of the Ministerial Submission and the contents of the documents attached to the Ministerial Submission as outlined at paragraph 12.

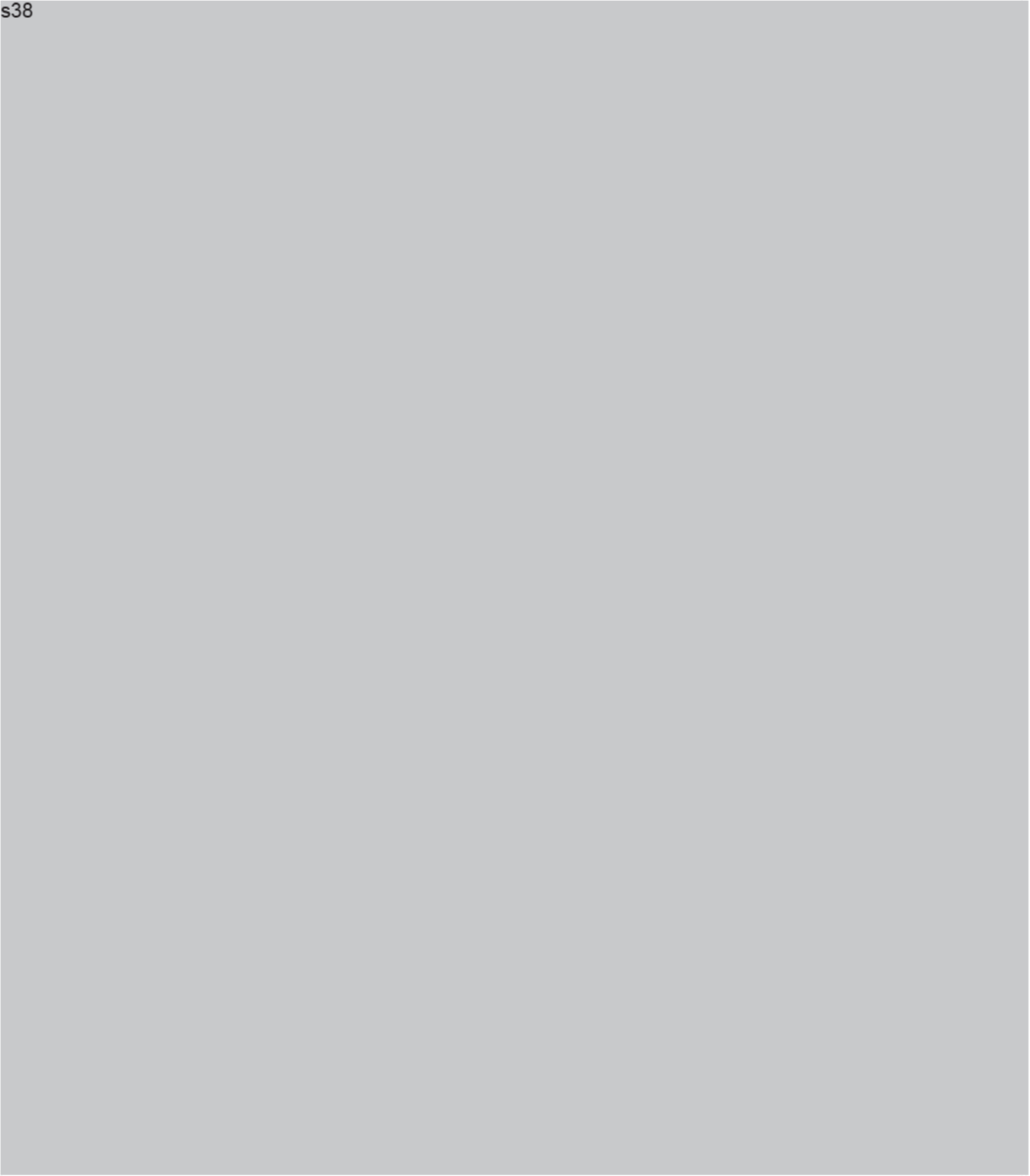
Submissions by the Applicant

19. The Applicant made submissions in the request for approval made under subsection 90B(1) of the Act on 2 February 2021. Those submissions included the following claims:

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Correspondences provided by the Applicant relating to the request for approvals38
A large rectangular area of the document is redacted with a solid grey fill.

s38  The Court has previously found that it is relevant to consider the existence of any community support, such as a petition, for the granting of approval, but that the presence of community support is not sufficient to meet the test of whether the granting of approval is in the public interest. Rather, it is necessary to consider whether granting approval would be in the public interest more generally.

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Findings on material questions of fact

22. Based on the material before me, I made the following findings of material facts.

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s38

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My Decision

23. I decided to approve the Applicant's request to supply pharmaceutical benefits at s38

Reasons for decision

24. I decided to approve the Applicant's request because I was satisfied that the criteria for the exercise of my discretion were met.
25. Specifically, I was satisfied that:
- the Secretary's decision to not approve the Applicant would result in a community being left without reasonable access to pharmaceutical benefits supplied by an approved pharmacist; and
 - it was in the public interest to approve the Applicant.

Relevant community

26. Paragraph 90A(3)(a) of the Act provides that for the purposes of subsection (2), community means a group of people that, in my opinion, constitute a community.

s38

Reasonable access

28. I considered whether a decision to not approve the proposed pharmacy would result in the community being left without reasonable access to pharmaceutical benefits, and had regard to the following:

s38

29. After weighing this point against the following, I was satisfied the community would be left without reasonable access to pharmaceutical benefits, should the Applicant's request not be approved:

s38

s38

Public interest

s38

31. I found however, that there is a public interest in the community having access to pharmaceutical benefits at the proposed location, as I considered that the pharmacy is in a location that will allow convenient access to pharmaceutical benefits for the community.



Greg Hunt **06 AUG 2021**

Encl: Attachment A: Extract of the relevant legislation

Released under the Freedom of Information Act 1982 by the Department of Health, Disability and Ageing

ATTACHMENT A**National Health Act 1953**

Sections 90A and 90B of the Act provide as follows:

90A Minister may substitute decision approving pharmacist

- (1) This section applies in relation to a decision of the Secretary under section 90 rejecting an application by a pharmacist for approval to supply pharmaceutical benefits at particular premises, if:
 - (a) the application was made on or after 1 July 2006; and
 - (b) the decision was made on the basis that the application did not comply with the requirements of the relevant rules determined by the Minister under section 99L.
- (2) The Minister may substitute for the Secretary's decision a decision approving the pharmacist for the purpose of supplying pharmaceutical benefits at the particular premises if the Minister is satisfied that:
 - (a) the Secretary's decision will result in a community being left without reasonable access to pharmaceutical benefits supplied by an approved pharmacist; and
 - (b) it is in the public interest to approve the pharmacist.
- (3) For the purposes of subsection (2):

community means a group of people that, in the opinion of the Minister, constitutes a community.

reasonable access, in relation to pharmaceutical benefits supplied by an approved pharmacist, means access that, in the opinion of the Minister, is reasonable.
- (4) The power under subsection (2) may only be exercised:
 - (a) on request by the pharmacist made under section 90B; and
 - (b) by the Minister personally.
- (5) Subject to subsection 90B(5), the Minister does not have a duty to consider whether to exercise the power under subsection (2) in respect of the Secretary's decision.
- (6) The power under subsection (2) does not authorise the Minister to approve a pharmacist for the purpose of supplying pharmaceutical benefits at particular premises at which the pharmacist is not permitted, under the law of the State or Territory in which the premises are situated, to carry on business.
- (7) A decision by the Minister not to exercise the power under subsection (2) in respect of the Secretary's decision does not prevent the pharmacist from making an application to the Administrative Appeals Tribunal under subsection 105AB(7) for review of the Secretary's decision.
- (8) For the purposes of this section (other than subsection (7)):
 - (a) a reference to a decision of the Secretary includes a reference to a decision of the Secretary that has been affirmed by a decision of the Administrative Appeals Tribunal or an order of a federal court; and
 - (b) a reference to a decision of the Administrative Appeals Tribunal includes a reference to a decision of the Administrative Appeals Tribunal that has been affirmed by an order of a federal court.

90B Request to Minister to approve pharmacist

- (1) If section 90A applies to a decision of the Secretary under section 90 rejecting an application by a pharmacist, the pharmacist may, in writing, request the Minister to exercise the Minister's power under subsection 90A(2) in respect of the Secretary's decision.
- (2) The Minister may determine the form in which a request under subsection (1) must be made and, if the Minister does so, such a request must be made in that form.
- (3) A request under subsection (1) must be made:
 - (a) within 30 days after the pharmacist is notified of the Secretary's decision; or
 - (b) if the pharmacist has applied to the Administrative Appeals Tribunal for review of the Secretary's decision—within 30 days after:

- (i) the pharmacist is given a copy of the Administrative Appeals Tribunal's decision affirming the Secretary's decision; or
 - (ii) the application has been discontinued, withdrawn or dismissed; or
- (c) if the pharmacist has sought an order from a federal court in respect of the Secretary's decision or a decision of the Administrative Appeals Tribunal affirming the Secretary's decision—within 30 days after:
 - (i) the court has made an order affirming the Secretary's decision or the Administrative Appeals Tribunal's decision, as the case requires; or
 - (ii) the court proceeding has been discontinued, withdrawn or dismissed.
- (4) The Minister must, within 3 months after receiving a request under subsection (1), personally decide whether to consider the request. If the Minister has not made a decision within this period, the Minister is taken to have decided not to consider the request.
- (5) If the Minister decides to consider a request under subsection (1), the Minister must, within 3 months after making that decision, personally decide whether to exercise the power under subsection 90A(2) in respect of the Secretary's decision. If the Minister has not made a decision within this period, the Minister is taken to have decided not to exercise the power under subsection 90A(2) in respect of the Secretary's decision.
- (6) The Secretary must, by notice in writing, advise the pharmacist of:
 - (a) the decision made, or taken to have been made, by the Minister under subsection (4); and
 - (b) if applicable, the decision made, or taken to have been made, by the Minister under subsection (5).

Released under the Freedom of Information Act 1982 by the Department of Health, Disability and Ageing

From: [90Apharmacy](#)
To: s47F
Subject: Request for ministerial discretion - s47F, s38 [SEC=OFFICIAL]
Date: Monday, 28 June 2021 4:17:08 PM
Attachments: [image001.png](#)
[s38 - Approval to Supply certificate.pdf](#)
[Notice of Minister's decision to approve s38 .pdf](#)
[Conditions of approval.pdf](#)
[Notification of bank account details for an approved pharmacy form.pdf](#)
[Authority to permit person\(s\) to enquire and-or sign claim forms on behalf of pharmacist\(s\).pdf](#)

Good afternoon Mr s47F

Please find attached correspondence in relation to your client's request to supply Pharmaceutical Benefits Scheme (PBS) medicines at s38

Please find attached PBS approval Certificate, PBS notification of Approval Letter and the *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017*.

The following documents are also attached for your completion and return via the PBS Approved Suppliers Portal.

- Notification of bank account details for approved pharmacist form
- Authority to authorise pharmacist(s) to sign claim forms on behalf of approved pharmacist(s) form

If you have questions in relation to the above, please email 90Apharmacy@health.gov.au.

Regards

s47E(c), s47F

Assistant Director

Benefits Integrity and Digital Health Division | Health Financing Group
 Provider Support and Systems Branch
 Australian Government Department of Health
 E: 90Apharmacy@health.gov.au
 GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.



Released under the Freedom of Information Act 1982 by the Department of Health, Disability and Ageing



Australian Government
Department of Health

Approval to Supply Pharmaceutical Benefits

National Health Act 1953

s38

with Approval Number: s38

trading as:

s38

has approval to supply pharmaceutical benefits at the premises situated at:

s38

effective from the **22nd** day of **June** in the year **2021**

s47F

Signature

Delegate, Department of Health

28 June 2021

Date



Australian Government
Department of Health

Our ref: DP323-E21-6055

s38

s47F

Dear Applicant

Notice of Approval

I, Harry Rothenfluh, delegate of the Secretary of the Department of Health under subsection 90B(6) of the *National Health Act 1953* (Act), am writing to notify you that on **22 June 2021**, the Minister for Health and Aged Care, the Hon Greg Hunt MP (Minister), approved:

s38

to supply Pharmaceutical Benefits Scheme (PBS) medicines at:

s38

The approval number that has been allocated to your approval by the delegate of the Minister under regulation 16 of the *National Health (Pharmaceutical Benefits) Regulations 2017* is s38. Please ensure that you reference this number on all official communications with us and when submitting PBS claims to Services Australia.

Enclosed is your 'Certificate of Approval' in respect of the above premises.

Conditions of approval

It is important to note that this approval is subject to the conditions specified in section 92A of the Act, including those determined by the Minister under subsection 92A(1)(f) of the Act (refer to *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017* attached).

As your application was originally made under s38 of the *National Health (Australian Community Pharmacy Authority Rules) Determination 2018* (the Pharmacy Location Rules), it is subject to the restrictions applicable to that Item (see Item 313 of the Pharmacy Location Rules).

As the approved pharmacist, it is your responsibility to:

- understand and comply with any changes to the legislation in the supply of Pharmaceutical Benefits;
- let us know of any changes that affect the supply of PBS medicines at the pharmacy premises; and
- notify us if changes occur to your pharmacy premises and/or the approved pharmacist/s.

Provision of bank account for PBS payments and authorising pharmacist(s) to submit claims

You will need to complete the following forms (attached) to enable payment of your PBS claims and/or to authorise a pharmacist to sign claim on your behalf:

- *Notification of bank account details for approved community pharmacist*
- *Authority to authorise pharmacist(s) to sign claim forms on behalf of approved pharmacist(s)*

These forms must be returned via the PBS Approved Suppliers Portal accessible at www.pbsapprovedsuppliers.health.gov.au

Pharmacy landline

As you have advised that the pharmacy is open and trading, you will need to advise us of the pharmacy's landline by emailing:
pbsapprovedsuppliers@health.gov.au

Online claiming of PBS

You must Register for Online claiming for PBS, and enter into a Recipient Created Tax Invoice Agreement with Services Australia.

These forms can be accessed at:

www.servicesaustralia.gov.au/organisations/health-professionals/enablers/register-online-claiming-pbs/32456

Ordering PBS stationery

To register to order PBS stationery, email The Cameron's Group at:
pbs@camerons.net

Once registered, your online account will allow you to order PBS stationery relevant to your approval.

Efficient Funding of Chemotherapy (EFC) arrangements

Should you wish to claim eligible EFC items you will need to obtain a Compounder ID for your pharmacy or the ID of the compounder used to prepare these medicines. More information on how to obtain a Compounder ID can be found at www.ccpsagency.com.au/compounderform.pdf

Community Pharmacy Programs

Please ensure that you advise the Pharmacy Program Administrator, the organisation responsible for administering Community Pharmacy Programs funded under the Seventh Community Pharmacy Agreement, of any changes to your PBS approval number.

If you have any enquiries regarding this letter, please email:

90Apharmacy@health.gov.au

Yours sincerely

s47E(c), s47F

Harry Rothenfluh PhD

Delegate of the Secretary of the Department of Health

28 June 2021

Attachments

Certificate of Approval

National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017

Notification of bank account details for approved pharmacist form

Authority to authorise pharmacist(s) to sign claim forms on behalf of approved pharmacist(s) form

From: [90Apharmacy](#)
To: s47F
Subject: Request for Statement of Reasons – s38 [SEC=OFFICIAL]
Date: Tuesday, 20 July 2021 4:18:45 PM
Attachments: [image001.png](#)
s38 - SoR Cover letter to third party.pdf
s38 - Signed SoR and Att A.pdf

Dear Ms s47F

Please find attached the Statement of Reasons and covering letter in relation to premises in s38

Regards

s47E(o),
s47F

Ministerial Discretion
PBS Approved Suppliers Section
Provider Support and Systems Branch
Australian Government Department of Health
E: 90Apharmacy@health.gov.au
MDP 659, PO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present



Building a stronger,
healthier country
Yesterday
today and
tomorrow

Released under the Freedom of Information Act 1982 by the Department of Health, Disability and Ageing



Australian Government

Department of Health

Our ref: DP323/E21-100797

Pharmacy Owner

s38

s47F

Dear Pharmacy Owner

Request for Statement of Reasons – s38

I refer to a request made on your behalf on 30 June 2021, for a Statement of Reasons under subsection 13(1) of the *Administrative Decisions (Judicial Review) Act 1977*, in relation to a decision made by the Minister for Health and Aged Care, the Hon Greg Hunt MP, on 22 June 2021, to exercise discretionary power to approve the supply of pharmaceutical benefits at s38.

Please find the Statement of Reasons attached. The Statement of Reasons sets out the findings on the material questions of fact, referring to the evidence or other material on which those findings were based, but does not include any information which must not be divulged under section 135A of the *National Health Act 1953*.

s47E(c), s47F

Assistant Director
PBS Approved Suppliers Section
Benefits Integrity and Digital Health Division
20 July 2021

Encl:



The Hon Greg Hunt MP
Minister for Health and Aged Care

Statement of Reasons

This statement is provided in response to a request made by s38

s38

s38 received on 30 June 2021, for a Statement of Reasons under section 13 of the *Administrative Decisions (Judicial Review) Act 1977*. This statement is made in relation to a decision made by me, as Minister for Health and Aged Care, under subsection 90A(2) of the *National Health Act 1953*, to substitute (for the Secretary's decision) a decision approving the Applicant for the purpose of supplying pharmaceutical benefits at s38 (proposed premises).

Definitions

In this statement:

'Act' means the *National Health Act 1953*;

'Applicant' means the pharmacist who applied: for approval under section 90 of the Act; and under subsection 90B(1) for me to exercise my discretion under subsection 90A(2) of the Act;

'Authority' means the Australian Community Pharmacy Authority established under section 99J of the Act;

'Location Rules' means the *National Health (Australian Community Pharmacy Authority Rules) Determination 2018* (PB 46 of 2018) made under section 99L of the Act;

'Ministerial Submission' means Ministerial Submission MS21-000378, provided by my Department on 7 June 2021, in relation to the request for approval by the Applicant made under subsection 90B(1) of the Act;

'proposed premises' means premises located at s38

s38

'Secretary' means the Secretary of the Department of Health;

'section 90 Application' means the application made by the Applicant on 7 September 2020 under section 90 of the Act for approval to supply pharmaceutical benefits at the proposed premises.

Background

1. On 7 September 2020, the Applicant made the section 90 application to the Secretary.
2. In accordance with subsection 90(3A) of the Act, the section 90 application was referred to the Authority for consideration in accordance with the Location Rules.
3. On 11 December 2020, the Authority recommended to a delegate of the Secretary that the Applicant's section 90 application not be approved because it was not satisfied it met
s38
4. Under section 11 of the Location Rules, the Authority must recommend that an application not be approved under section 90 of the Act if a requirement under the Location Rule that applies to the application is not met.
5. On 23 December 2020, the Secretary's delegate rejected the application. This was in accordance with subsection 90(3B) of the Act, as the Authority had recommended the application not be approved.

Request for exercise of Discretionary Power

6. Under subsection 90B(1) of the Act, if section 90A applies to a rejection under section 90, a pharmacist can lodge a request with my Department for me to exercise my discretionary power under subsection 90A(2) of the Act. Subsection 90A(2) of the Act provides that I may, in certain circumstances, substitute a rejection by the Secretary of delegate under section 90 with an approval decision.
 7. On 22 January 2021, my Department received a request from the Applicant for the exercise of my discretion to approve the Applicant to supply pharmaceutical benefits at the proposed premises.
 8. On 24 March 2021, in accordance with subsection 90B(4) of the Act, I decided to consider the Applicant's request.
- s38

s38

Exercise of discretionary power

13. On 22 June 2021, I decided, in accordance with subsection 90A(2) of the Act, to exercise my discretion to approve the Applicant's request to supply pharmaceutical benefits at the proposed premises.

s38

17. An extract of the relevant legislation is at Attachment A.

Evidence taken into account

18. In considering the exercise of my discretion and making my decision, I took into account the contents of the Ministerial Submission and the contents of the documents attached to the Ministerial Submission as outlined at paragraph 12.

Submissions by the Applicant

19. The Applicant made submissions in the request for approval made under subsection 90B(1) of the Act on 22 January 2021. Those submissions included the following claims:

s38

Correspondences provided by the Applicant relating to the request for approval

s38

The

Court has previously found that it is relevant to consider the existence of any community support, such as a petition, for the granting of approval, but that the presence of community support is not sufficient to meet the test of whether the granting of approval is in the public interest. Rather, it is necessary to consider whether granting approval would be in the public interest more generally.

Submissions from third parties in response to my Department's notices

20. The submissions received from third parties in response to the notices issued under section 90(D) included the following:

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s38
**Findings on material questions of fact**

21. Based on the material before me, I made the following findings of material facts.

Ageing

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My Decision

22. I decided to approve the Applicant's request to supply pharmaceutical benefits at s38

Reasons for decision

23. I decided to approve the Applicant's request because I was satisfied that the criteria for the exercise of my discretion were met.
24. Specifically, I was satisfied that:
- the Secretary's decision to not approve the Applicants would result in a community being left without reasonable access to pharmaceutical benefits supplied by an approved pharmacist; or
 - that it was in the public interest to approve the Applicant.

Relevant community

25. Paragraph 90A(3)(a) of the Act provides that for the purposes of subsection (2), community means a group of people that, in my opinion, constitute a community.
26. Having regard to the information and submissions provided by the Applicant, my Department and third parties, I formed the view that there is a relevant community that would be affected by the proposed pharmacy not being approved. That community
- s38

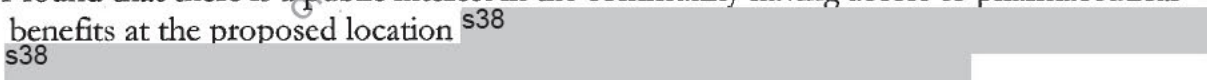
Reasonable access

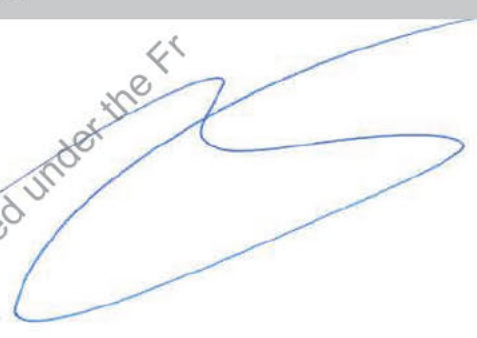
27. I considered whether a decision to not approve the proposed pharmacy would result in the community being left without reasonable access to pharmaceutical benefits, and had regard to the following:

s38


28. After weighing this point against the following, I was satisfied the community would be left without reasonable access to pharmaceutical benefits, should the Applicant's request be not be approved:

s38
***Public interest***

29. I found that there is a public interest in the community having access to pharmaceutical benefits at the proposed location s38
s38 


Released under the Fr
Greg Hunt

14 JUL 2021

Encl: Attachment A: Extract of the relevant legislation

ATTACHMENT A**National Health Act 1953**

Sections 90A and 90B of the Act provide as follows:

90A Minister may substitute decision approving pharmacist

- (1) This section applies in relation to a decision of the Secretary under section 90 rejecting an application by a pharmacist for approval to supply pharmaceutical benefits at particular premises, if:
 - (a) the application was made on or after 1 July 2006; and
 - (b) the decision was made on the basis that the application did not comply with the requirements of the relevant rules determined by the Minister under section 99L.
- (2) The Minister may substitute for the Secretary's decision a decision approving the pharmacist for the purpose of supplying pharmaceutical benefits at the particular premises if the Minister is satisfied that:
 - (a) the Secretary's decision will result in a community being left without reasonable access to pharmaceutical benefits supplied by an approved pharmacist; and
 - (b) it is in the public interest to approve the pharmacist.
- (3) For the purposes of subsection (2):

community means a group of people that, in the opinion of the Minister, constitutes a community.

reasonable access, in relation to pharmaceutical benefits supplied by an approved pharmacist, means access that, in the opinion of the Minister, is reasonable.
- (4) The power under subsection (2) may only be exercised:
 - (a) on request by the pharmacist made under section 90B; and
 - (b) by the Minister personally.
- (5) Subject to subsection 90B(5), the Minister does not have a duty to consider whether to exercise the power under subsection (2) in respect of the Secretary's decision.
- (6) The power under subsection (2) does not authorise the Minister to approve a pharmacist for the purpose of supplying pharmaceutical benefits at particular premises at which the pharmacist is not permitted, under the law of the State or Territory in which the premises are situated, to carry on business.
- (7) A decision by the Minister not to exercise the power under subsection (2) in respect of the Secretary's decision does not prevent the pharmacist from making an application to the Administrative Appeals Tribunal under subsection 105AB(7) for review of the Secretary's decision.
- (8) For the purposes of this section (other than subsection (7)):
 - (a) a reference to a decision of the Secretary includes a reference to a decision of the Secretary that has been affirmed by a decision of the Administrative Appeals Tribunal or an order of a federal court; and
 - (b) a reference to a decision of the Administrative Appeals Tribunal includes a reference to a decision of the Administrative Appeals Tribunal that has been affirmed by an order of a federal court.

90B Request to Minister to approve pharmacist

- (1) If section 90A applies to a decision of the Secretary under section 90 rejecting an application by a pharmacist, the pharmacist may, in writing, request the Minister to exercise the Minister's power under subsection 90A(2) in respect of the Secretary's decision.
- (2) The Minister may determine the form in which a request under subsection (1) must be made and, if the Minister does so, such a request must be made in that form.
- (3) A request under subsection (1) must be made:
 - (a) within 30 days after the pharmacist is notified of the Secretary's decision; or
 - (b) if the pharmacist has applied to the Administrative Appeals Tribunal for review of the Secretary's decision—within 30 days after:

- (i) the pharmacist is given a copy of the Administrative Appeals Tribunal's decision affirming the Secretary's decision; or
 - (ii) the application has been discontinued, withdrawn or dismissed; or
- (c) if the pharmacist has sought an order from a federal court in respect of the Secretary's decision or a decision of the Administrative Appeals Tribunal affirming the Secretary's decision—within 30 days after:
 - (i) the court has made an order affirming the Secretary's decision or the Administrative Appeals Tribunal's decision, as the case requires; or
 - (ii) the court proceeding has been discontinued, withdrawn or dismissed.
- (4) The Minister must, within 3 months after receiving a request under subsection (1), personally decide whether to consider the request. If the Minister has not made a decision within this period, the Minister is taken to have decided not to consider the request.
- (5) If the Minister decides to consider a request under subsection (1), the Minister must, within 3 months after making that decision, personally decide whether to exercise the power under subsection 90A(2) in respect of the Secretary's decision. If the Minister has not made a decision within this period, the Minister is taken to have decided not to exercise the power under subsection 90A(2) in respect of the Secretary's decision.
- (6) The Secretary must, by notice in writing, advise the pharmacist of:
 - (a) the decision made, or taken to have been made, by the Minister under subsection (4); and
 - (b) if applicable, the decision made, or taken to have been made, by the Minister under subsection (5).

Released under the Freedom of Information Act 1982 by the Department of Health, Disability and Ageing

From: [90Apharmacy](#)
To: s47F
Cc: [90Apharmacy](#)
Subject: Request for ministerial discretion - s38 [SEC=OFFICIAL]
Date: Friday, 26 March 2021 9:52:39 AM
Attachments: [image001.png](#)
[image002.jpg](#)
[Notice of Minister s decision to approve - s38 .pdf](#)
[s38 - Approval to Supply certificate - s38 .pdf](#)
[Conditions of approval.pdf](#)
[Notification of bank account details for an approved pharmacist form.pdf](#)
[Authority to permit person\(s\) to enquire and-or sign claim forms on behalf of pharmacist\(s\).pdf](#)

Good afternoon Mr s47F

Please find attached correspondence in relation to your client's request to supply Pharmaceutical Benefits Scheme (PBS) medicines at s38

Please find attached PBS approval Certificate, PBS Approval Letter and the *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017*.

The following documents are also attached for your completion and return via the PBS Approved Suppliers Portal.

- Notification of bank account details for approved pharmacist form
- Authority to authorise pharmacist(s) to sign claim forms on behalf of approved pharmacist(s) form

If you have questions in relation to the above, please email us at 90Apharmacy@health.gov.au.

Regards

s47E(c), s47F

Assistant Director

Benefits Integrity and Digital Health Division | Health Financing Group

Provider Support and Systems Branch

Australian Government Department of Health

E: 90Apharmacy@health.gov.au

GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present

100 years signature block_ver32





Australian Government
Department of Health

Our ref: DP313/E20-273519
 s38

s47F

Dear Applicant

Notice of Approval

I, Harry Rothenfluh, delegate of the Secretary of the Department of Health under subsection 90B(6) of the *National Health Act 1953* (Act), am writing to notify you that on **21 March 2021**, the Minister for Health and Aged Care, the Hon Greg Hunt MP (Minister), approved:

s38

to supply Pharmaceutical Benefits Scheme (PBS) medicines at:

s38

The approval number that has been allocated to your approval by the delegate of the Minister under regulation 16 of the *National Health (Pharmaceutical Benefits) Regulations 2017* is s38. Please ensure that you reference this number on all official communications with us and when submitting PBS claims to Services Australia.

Enclosed is your 'Certificate of Approval' in respect of the above premises.

Conditions of approval

It is important to note that this approval is subject to the conditions specified in section 92A of the Act, including those determined by the Minister under subsection 92A(1)(f) of the Act (refer to *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017* attached).

As your application was originally made under **s38** of the *National Health (Australian Community Pharmacy Authority Rules) Determination 2018* (the Pharmacy Location Rules), it is subject to the restrictions applicable to that Item (see Item 315 of the Pharmacy Location Rules).

As the approved pharmacist, it is your responsibility to:

- understand and comply with any changes to the legislation in the supply of Pharmaceutical Benefits;
- let us know of any changes that affect the supply of PBS medicines at the pharmacy premises; and
- notify us if changes occur to your pharmacy premises and/or the approved pharmacist/s.

Provision of bank account for PBS payments and authorising pharmacist(s) to submit claims

You will need to complete the following forms (attached) to enable payment of your PBS claims and/or to authorise a pharmacist to sign claim on your behalf:

- *Notification of bank account details for approved community pharmacist*
- *Authority to authorise pharmacist(s) to sign claim forms on behalf of approved pharmacist(s)*

These forms must be returned via the PBS Approved Suppliers Portal accessible at www.pbsapprovedsuppliers.health.gov.au

Pharmacy landline

As you have advised that the pharmacy is open and trading, you will need to advise us of the pharmacy's landline by emailing:
pbsapprovedsuppliers@health.gov.au

Online claiming of PBS

You must Register for Online claiming for PBS, and enter into a Recipient Created Tax Invoice Agreement with Services Australia.

These forms can be accessed at:

www.servicesaustralia.gov.au/organisations/health-professionals/enablers/register-online-claiming-pbs/32456

Ordering PBS stationery

To register to order PBS stationery, email The Cameron's Group at:
pbs@camerons.net

Once registered, your online account will allow you to order PBS stationery relevant to your approval.

Efficient Funding of Chemotherapy (EFC) arrangements

Should you wish to claim eligible EFC items you will need to obtain a Compounder ID for your pharmacy or the ID of the compounder used to prepare these medicines. More information on how to obtain a Compounder ID can be found at www.ccpsagency.com.au/compounderform.pdf

Community Pharmacy Programs

Please ensure that you advise the Pharmacy Program Administrator, the organisation responsible for administering Community Pharmacy Programs funded under the Seventh Community Pharmacy Agreement, of any changes to PBS approval number.

If you have any enquiries regarding this letter, please email:

90Apharmacy@health.gov.au

Yours sincerely

s47E(c), s47F

Harry Rothenfluh PhD

Delegate of the Secretary of the Department of Health

25 March 2021

Attachments

Certificate of Approval

National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017

Notification of bank account details for approved pharmacist form

Authority to authorise pharmacist(s) to sign claim forms on behalf of approved pharmacist(s) form



Australian Government
Department of Health

Approval to Supply Pharmaceutical Benefits

National Health Act 1953

s38

with Approval Number: s38

trading as:

s38

has approval to supply pharmaceutical benefits at the premises situated at:

s38

effective from the **21st** day of **March** in the year **2021**

s47F

Delegate, Department of Health

25 March 2021

Date

From: [90Apharmacy](#)
To: s47F
Cc: [90Apharmacy](#)
Subject: Request for Ministerial Approval - s38 [SEC=OFFICIAL]
Date: Friday, 8 January 2021 3:47:05 PM
Attachments: [image001.png](#)
[Notice of Minister's decision to approve - s38 .pdf](#)
[Approval to Supply Certificate - s38 .pdf](#)
[Conditions of approval.pdf](#)
[Notification of bank account details for an approved pharmacist form.pdf](#)
[Authority to permit person\(s\) to enquire and/or sign claim forms on behalf of pharmacist\(s\).pdf](#)

Good afternoon Mr s47F

Please find attached correspondence in relation to your client's request to supply Pharmaceutical Benefits Scheme (PBS) medicines at s38

Please find attached PBS approval Certificate, PBS Approval Letter and the *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017*.

The following documents are also attached for your completion and return to the email address given below :

- Notification of bank account details for approved pharmacist form
- Authority to authorise pharmacist(s) to sign claim forms on behalf of approved pharmacist(s) form

If you have questions in relation to the above, please email us at 90Apharmacy@health.gov.au.

Regards

s47E(o),
s47F

Benefits Integrity and Digital Health Division | Health Financing Group
 Provider Support and Systems Branch
 Australian Government Department of Health
 E: 90Apharmacy@health.gov.au
 GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present



Australian Government
Department of Health

Our ref: DP301/E20-251413

s47F

Dear Applicant

Notice of Approval

I, Luke Bricknell, delegate of the Secretary of the Department of Health under subsection 90B(6) of the *National Health Act 1953* (Act), am writing to notify you that on **22 December 2020**, the Minister for Health and Aged Care, the Hon Greg Hunt MP (Minister), approved:

s38

To supply Pharmaceutical Benefits Scheme (PBS) medicines at:

s38

The approval number that has been allocated to your approval by the delegate of the Minister under regulation 16 of the *National Health (Pharmaceutical Benefits) Regulations 2017* is s38. Please ensure that you reference this number on all official communications with us and when submitting PBS claims to Services Australia.

Enclosed is your "Certificate of Approval" in respect of the above premises.

Conditions of approval

It is important to note that this approval is subject to the conditions specified in section 92A of the Act, including those determined by the Minister under subsection 92A(1)(f) of the Act (refer to *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017* attached).

As your application was originally made under s38 of the *National Health (Australian Community Pharmacy Authority Rules) Determination 2018* (Pharmacy Location Rules), it is subject to the restrictions applicable to that Item (see Item 314 of the Pharmacy Location Rules).

As the approved pharmacist, it is your responsibility to:

- understand and comply with any changes to the legislation in the supply of Pharmaceutical Benefits;
- let us know of any changes that affect the supply of Pharmaceutical Benefits Scheme (PBS) medicines at the pharmacy premises; and
- notify us if changes occur to your pharmacy premises and/or the approved pharmacist/s.

Provision of bank account for PBS payments and authorising pharmacist(s) to submit claims

You will need to complete the following forms (attached) to enable payment of your PBS claims and/or to authorise a pharmacist to sign claim on your behalf:

- *Notification of bank account details for approved community pharmacist*
- *Authority to authorise pharmacist(s) to sign claim forms on behalf of approved pharmacist(s)*

These forms must be returned via the PBS Approved Suppliers Portal.

Pharmacy landline

Once the pharmacy is open and trading, you will need to advise the Department of the pharmacy's landline by emailing us at:

pbsapprovesuppliers@health.gov.au

Online claiming of PBS

You must Register for Online claiming for PBS, and enter into a Recipient Created Tax Invoice Agreement with Services Australia.

These forms can be accessed at:

www.servicesaustralia.gov.au/organisations/health-professionals/enablers/register-online-claiming-pbs/32456.

Ordering PBS stationery

To register to order PBS stationery, email The Cameron's Group at:

pbs@camerons.net

Once registered, your online account will allow you to order PBS stationery relevant to your approval.

Efficient Funding of Chemotherapy (EFC) arrangements

Should you wish to claim eligible EFC items you will need to obtain a Compounder ID for your pharmacy or the ID of the compounder used to prepare these medicines. More information on how to obtain a Compounder ID can be found at www.ccpsagency.com.au/compounderform.pdf.

If you have any enquiries regarding this letter, please email:
90Apharmacy@health.gov.au.

Yours sincerely

s47E(c), s47F



Luke Bricknell
Delegate of the Secretary of the Department of Health
8 January 2021

Attachments

Certificate of Approval

National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017

Notification of bank account details for approved pharmacist form

Authority to authorise pharmacist(s) to sign claim forms on behalf of approved pharmacist(s) form

Released under the Freedom of Information Act 1982 by the Department of Health, Disability and Ageing



Australian Government
Department of Health

Approval to Supply Pharmaceutical Benefits

National Health Act 1953

s38

with approval number: s38

trading as

s38

has approval to supply pharmaceutical benefits at the premises situated at

s38

effective from the 22nd day of **December** in the year **2020**.

s47F

Delegate, Department of Health

8 January 2021

Date

From: [90Apharmacy](#)
To: s47F
Subject: Request for Statement of Reasons - s38 [SEC=OFFICIAL]
Date: Tuesday, 9 February 2021 6:33:17 PM
Attachments: [image001.png](#)
[SoR - covering letter - s38 .pdf](#)
[Signed SoR and Attachment A\(2\).pdf](#)

Dear Mr s47F

Please find attached the Statement of Reasons and covering letter in relation to premises in s38

Regards, s47E(c),
s47F

Ministerial Discretion
PBS Approved Suppliers Section
Provider Support and Systems Branch
Australian Government Department of Health
E: 90Apharmacy@health.gov.au
MDP 659, PO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present

Released under the Freedom of Information Act 1982 by the Department of Health, Disability and Ageing



Australian Government

Department of Health

Our ref: DP301/E20-251413

s38

s47F

s47F

s47F

Dear Pharmacist

Request for Statement of Reasons – s38

I refer to a request made on your behalf on 18 January 2021, for a Statement of Reasons under subsection 13(1) of the *Administrative Decisions (Judicial Review) Act 1977*, in relation to a decision made by the Minister for Health and Aged Care, the Hon Greg Hunt MP, on 22 December 2020, to approve a pharmacist to supply pharmaceutical benefits at s38

Please find the Statement of Reasons attached. The Statement of Reasons sets out the findings on the material questions of fact, referring to the evidence or other material on which those findings were based, but does not include any information which must not be divulged under section 135A of the *National Health Act 1953*.

s47E(c), s47F

Assistant Director
PBS Approved Suppliers Section
Benefits Integrity and Digital Health Division
9 February 2021

Encl:



The Hon Greg Hunt MP
Minister for Health and Aged Care

Statement of Reasons

This statement is provided in response to a request made by s38

s38

s38

received on 18 January 2021, for a Statement of Reasons under section 13 of the *Administrative Decisions (Judicial Review) Act 1977*.

This statement is made in relation to a decision (**Decision**) I made on 22 December 2020 under subsection 90A(2) of the *National Health Act 1953*, to substitute (for the Secretary's decision) a decision approving the Applicant for the purpose of supplying Pharmaceutical Benefits Scheme (PBS) medicines at s38 (proposed premises).

Definitions

In this statement:

'Act' means the *National Health Act 1953*;

'Applicant' means the pharmacist who applied for approval under section 90 of the Act; and under subsection 90B(1) for me to exercise my discretion under subsection 90A(2) of the Act;

'Authority' means the Australian Community Pharmacy Authority established under section 99J of the Act;

'Location Rules' means the *National Health (Australian Community Pharmacy Authority Rules) Determination 2018* (PB 46 of 2018) made under section 99L of the Act;

'Ministerial Submission' means Ministerial Submission MS20-001170, dated 22 December 2020, provided by my Department on 30 November 2020 in relation to the request for approval by the Applicant made under subsection 90B(1) of the Act;

'PBS medicines' means pharmaceutical benefits supplied in accordance with the Act;

'proposed premises' means premises located at s38

'Secretary' means the Secretary of the Department of Health;

'section 90 Application' means the application made on 20 April 2020 under section 90 of the Act for approval to supply PBS medicines at the proposed premises.

Background

1. On 20 April 2020, the Applicant made the section 90 application to the Secretary.
2. In accordance with subsection 90(3A) of the Act, the section 90 application was referred to the Authority for consideration in accordance with the Location Rules.
3. On 22 May 2020, the Authority recommended to a delegate of the Secretary that the Applicant's section 90 application not be approved because it was not satisfied it met the
s38
4. Under section 11 of the Location Rules, the Authority must recommend that an application not be approved under section 90 of the Act if a requirement under the Location Rule that applies to the application is not met.
5. On 15 June 2020, the Secretary's delegate rejected the application. This was in accordance with subsection 90(3B) of the Act, as the Authority had recommended the application not be approved.

Request for exercise of Discretionary Power

6. Under subsection 90B(1) of the Act, if section 90A applies to a rejection under section 90, a pharmacist can lodge a request with my Department for me to exercise my discretionary power under subsection 90A(2) of the Act. Subsection 90A(2) of the Act provides that I may, in certain circumstances, substitute a rejection by the Secretary of delegate under section 90 with an approval decision.
7. On 17 July 2020, my Department received a request from the Applicant for the exercise of my discretion to approve the Applicant to supply PBS medicines at the proposed premises.
s38

s38

Exercise of discretionary power

14. On 22 December 2020, I decided, in accordance with subsection 90A(2) of the Act, to exercise my discretion to approve the Applicant's request to supply PBS medicines at the proposed premises.

s38

Evidence taken into account

17. In considering the exercise of my discretion and making my decision, I took into account the contents of the Ministerial Submission and the contents of the documents attached to the Ministerial Submission.

Submissions by the Applicant

18. The Applicant made submissions in the request for approval made under subsection 90B(1) of the Act on 17 July 2020. Those submissions included the following claims:

s38

s38



Correspondences provided by the Applicant relating to the request for approval

s38



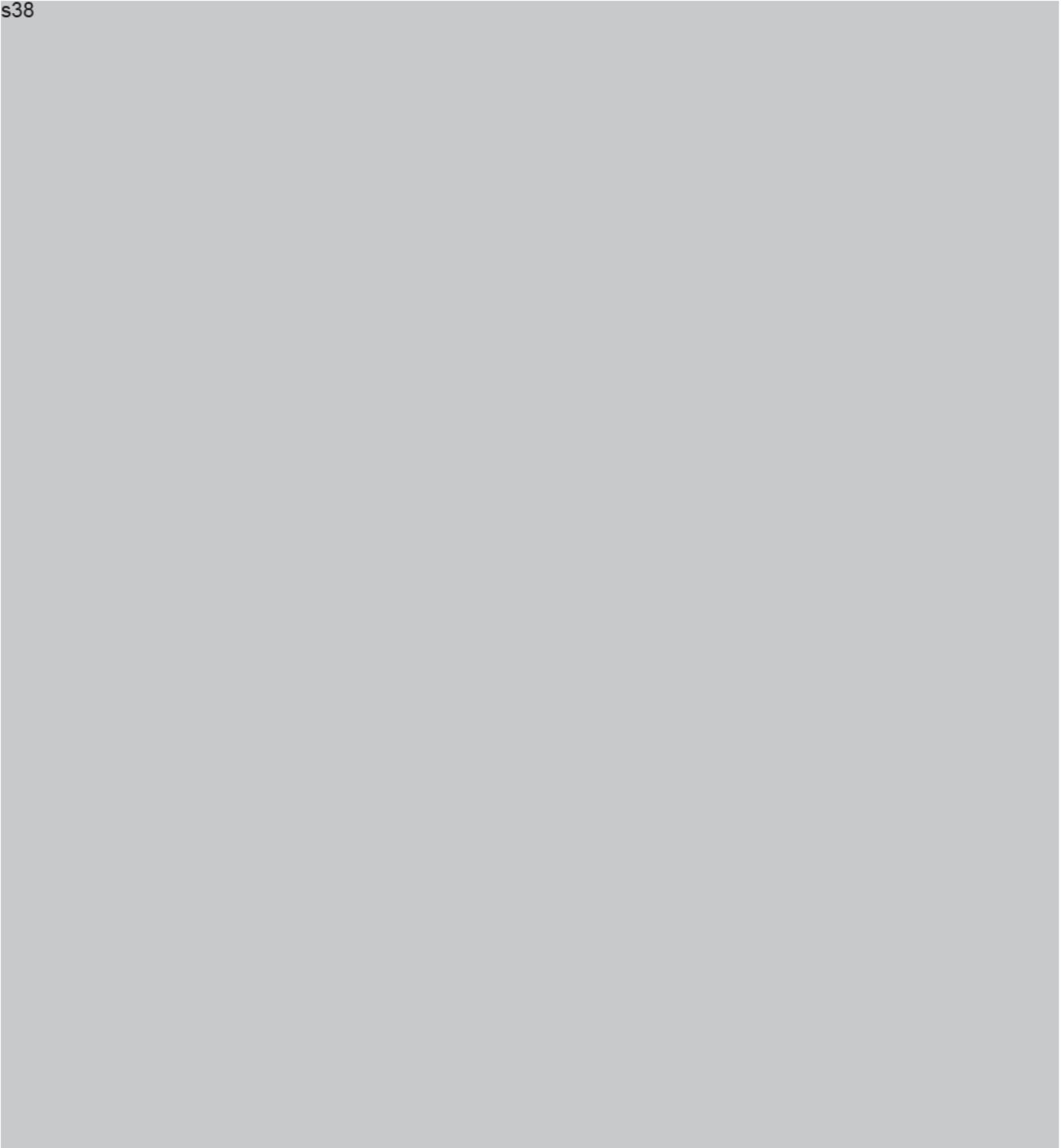
s38



Submissions from third parties in response to my Department's notices

19. The submissions received from third parties in response to the notices issued under section 90(D) included the following:

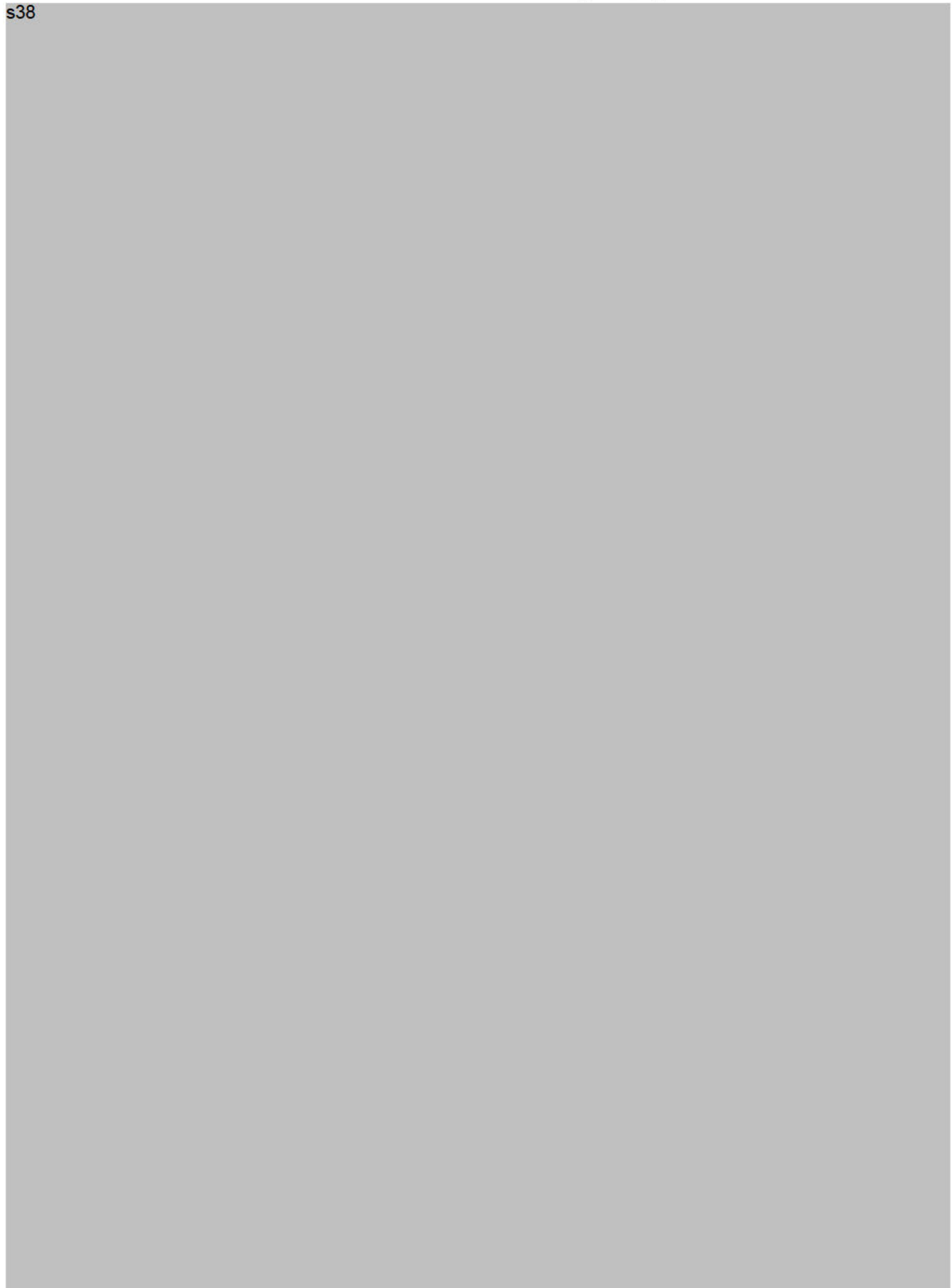
s38



Findings on material questions of fact

20. Based on the material before me, I made the following findings of material facts.

s38



s38

Reasons for decision

21. In making my decision, I was satisfied that the criteria for the exercise of my discretion are met.
22. Specifically, I was satisfied that:
 - The Secretary's decision to not approve the Applicant would result in a community being left without reasonable access to PBS medicines supplied by an approved pharmacist (s 90A(2)(a) of the Act); and
 - It was in the public interest to approve the Applicant (s 90A(2)(b) of the Act).

Community

23. Paragraph 90A(3)(a) of the Act provides that for the purposes of subsection (2), community means a group of people that, in my opinion, constitute a community.
24. Having regard to the information and submissions provided by the Department, the Applicant and third parties, I formed the view that there is a relevant community that would be affected by the proposed pharmacy not being approved. That community is

s38

Reasonable access to PBS medicines

25. I considered whether a decision to not approve the proposed pharmacy would result in the community being left without reasonable access to PBS medicines, and had regard to the following:

s38

26. After weighing these points against the following, I was satisfied a community would be left without reasonable access to PBS medicines, should the Applicant's request not be approved:

s38

- I considered it unreasonable for members of the Evandale community to travel more than 8 km to access PBS medicines, particularly given the high proportion of elderly residents in Evandale.

27. In all of the circumstances, I found that a decision not to approve the proposed premises would result in the community being left without reasonable access to PBS medicines.

Public interest

28. I found that there is a public interest in the community having access to PBS medicines at the proposed location ^{s38}

^{s38} I also found that the proposed premises is in a location that will allow convenient access to PBS medicines for the community.

s38

30. On balance, I found that it was in the public interest to approve the Applicant.



Greg Hunt

Encl: Attachment A: Extract of the relevant legislation

-4 FEB 2021

Released under the Freedom of Information Act 1982 by the Department of Health and Ageing

ATTACHMENT A**National Health Act 1953**

Sections 90A and 90B of the Act provide as follows:

90A Minister may substitute decision approving pharmacist

- (1) This section applies in relation to a decision of the Secretary under section 90 rejecting an application by a pharmacist for approval to supply pharmaceutical benefits at particular premises, if:
 - (a) the application was made on or after 1 July 2006; and
 - (b) the decision was made on the basis that the application did not comply with the requirements of the relevant rules determined by the Minister under section 99L.
- (2) The Minister may substitute for the Secretary's decision a decision approving the pharmacist for the purpose of supplying pharmaceutical benefits at the particular premises if the Minister is satisfied that:
 - (a) the Secretary's decision will result in a community being left without reasonable access to pharmaceutical benefits supplied by an approved pharmacist; and
 - (b) it is in the public interest to approve the pharmacist.
- (3) For the purposes of subsection (2):

community means a group of people that, in the opinion of the Minister, constitutes a community.

reasonable access, in relation to pharmaceutical benefits supplied by an approved pharmacist, means access that, in the opinion of the Minister, is reasonable.
- (4) The power under subsection (2) may only be exercised:
 - (a) on request by the pharmacist made under section 90B; and
 - (b) by the Minister personally.
- (5) Subject to subsection 90B(5), the Minister does not have a duty to consider whether to exercise the power under subsection (2) in respect of the Secretary's decision.
- (6) The power under subsection (2) does not authorise the Minister to approve a pharmacist for the purpose of supplying pharmaceutical benefits at particular premises at which the pharmacist is not permitted, under the law of the State or Territory in which the premises are situated, to carry on business.
- (7) A decision by the Minister not to exercise the power under subsection (2) in respect of the Secretary's decision does not prevent the pharmacist from making an application to the Administrative Appeals Tribunal under subsection 105AB(7) for review of the Secretary's decision.
- (8) For the purposes of this section (other than subsection (7)):
 - (a) a reference to a decision of the Secretary includes a reference to a decision of the Secretary that has been affirmed by a decision of the Administrative Appeals Tribunal or an order of a federal court; and
 - (b) a reference to a decision of the Administrative Appeals Tribunal includes a reference to a decision of the Administrative Appeals Tribunal that has been affirmed by an order of a federal court.

90B Request to Minister to approve pharmacist

- (1) If section 90A applies to a decision of the Secretary under section 90 rejecting an application by a pharmacist, the pharmacist may, in writing, request the Minister to exercise the Minister's power under subsection 90A(2) in respect of the Secretary's decision.
- (2) The Minister may determine the form in which a request under subsection (1) must be made and, if the Minister does so, such a request must be made in that form.
- (3) A request under subsection (1) must be made:
 - (a) within 30 days after the pharmacist is notified of the Secretary's decision; or
 - (b) if the pharmacist has applied to the Administrative Appeals Tribunal for review of the Secretary's decision—within 30 days after:

- (i) the pharmacist is given a copy of the Administrative Appeals Tribunal's decision affirming the Secretary's decision; or
 - (ii) the application has been discontinued, withdrawn or dismissed; or
- (c) if the pharmacist has sought an order from a federal court in respect of the Secretary's decision or a decision of the Administrative Appeals Tribunal affirming the Secretary's decision—within 30 days after:
 - (i) the court has made an order affirming the Secretary's decision or the Administrative Appeals Tribunal's decision, as the case requires; or
 - (ii) the court proceeding has been discontinued, withdrawn or dismissed.
- (4) The Minister must, within 3 months after receiving a request under subsection (1), personally decide whether to consider the request. If the Minister has not made a decision within this period, the Minister is taken to have decided not to consider the request.
- (5) If the Minister decides to consider a request under subsection (1), the Minister must, within 3 months after making that decision, personally decide whether to exercise the power under subsection 90A(2) in respect of the Secretary's decision. If the Minister has not made a decision within this period, the Minister is taken to have decided not to exercise the power under subsection 90A(2) in respect of the Secretary's decision.
- (6) The Secretary must, by notice in writing, advise the pharmacist of:
 - (a) the decision made, or taken to have been made, by the Minister under subsection (4); and
 - (b) if applicable, the decision made, or taken to have been made, by the Minister under subsection (5).

Released under the Freedom of Information Act 1982 by the Department of Health, Disability and Ageing

From: [90Apharmacy](#)
To: s47F
Subject: Notice of Approval - s38 [SEC=OFFICIAL]
Date: Wednesday, 11 March 2020 9:11:53 AM
Attachments: [image001.png](#)
[Notice of Ministers decision to approve - s38 .pdf](#)
[Approval to Supply certificate - s38 .pdf](#)
[Conditions of approval.pdf](#)
[Authority to authorise pharmacist\(s\) to sign claim forms on behalf of approved pharmacist form \(NEW\).pdf](#)
[Notification of bank account details for an approved pharmacist form \(NEW\).pdf](#)

Good morning s47F

Please find attached correspondence in relation to your client's request to supply Pharmaceutical Benefits Scheme (PBS) medicines at s38

Please find attached PBS approval Certificate, PBS Approval Letter and *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017*.

Please complete the following documents and return to the email address given below:

- Notification of bank account details for approved pharmacist form
- Authority to authorise pharmacist(s) to sign claim forms on behalf of approved pharmacist(s) form

If the pharmacy is not currently open and trading, your client will need to request the approval be deactivated until it is ready to open.

If you have questions in relation to the above, please email us at 90Apharmacy@health.gov.au.

Regards

s47E(c),
s47F
Assistant Director

Provider Benefits Integrity Division | Health Financing Group
 Compliance Systems Branch
 Australian Government Department of Health
 T: 02 6289 2425 | E: 90Apharmacy@health.gov.au
 GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.



Australian Government
Department of Health

Ref No: DP272/E19-107831

s47F

Dear Mr s47F

Notice of Approval

I, Harry Rothenfluh, delegate of the Secretary of the Department of Health under subsection 90B(6) of the *National Health Act 1953* (the Act), am writing to notify you that on **1 March 2020**, the Minister for Health, the Hon Greg Hunt MP (the Minister), approved:

s38

To supply Pharmaceutical Benefits Scheme (PBS) medicines at:

s38

The approval number that has been allocated to your approval by the delegate of the Minister under regulation 16 of the *National Health (Pharmaceutical Benefits) Regulations 2017* is s38. Please ensure that you reference this number on all official communications with us and when submitting PBS claims to Services Australia.

Enclosed is your 'Certificate of Approval' in respect of the above premises.

Conditions of approval

It is important to note that this approval is subject to the conditions specified in section 92A of the Act, including those determined by the Minister under subsection 92A(1)(f) of the Act (refer to *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017* attached).

As your application was made under s38 of the *National Health (Australian Community Pharmacy Authority Rules) Determination 2018* (the Pharmacy Location Rules), it is subject to the restrictions applicable to that Item (see Item 316 of the Pharmacy Location Rules).

As the approved pharmacist, it is your responsibility to:

- understand and comply with any changes to the legislation in the supply of Pharmaceutical Benefits;
- let us know of any changes that affect the supply of Pharmaceutical Benefits Scheme (PBS) medicines at the pharmacy premises; and
- notify us if changes occur to your pharmacy premises and/or the approved pharmacist/s.

Provision of bank account for PBS payments and authorising pharmacist(s) to submit claims

You will need to complete the following forms (attached) to enable payment of your PBS claims and/or to authorise a pharmacist to sign claim on your behalf:

- *Notification of bank account details for approved community pharmacist*
- *Authority to authorise pharmacist(s) to sign claim forms on behalf of approved pharmacist(s)*

These forms must be returned via the [PBS Approved Suppliers Portal](#).

Pharmacy landline

Once the pharmacy is open and trading you will need to advise Department of the pharmacy's landline by emailing us at pbsapprovesuppliers@health.gov.au.

Online claiming of PBS

You must Register for Online claiming for PBS, and enter into a Recipient Created Tax Invoice Agreement with Services Australia.

These forms can be accessed at:

<https://www.servicesaustralia.gov.au/organisations/health-professionals/enablers/register-online-claiming-pbs/32456>.

Ordering PBS stationery

To register to order PBS stationery, email The Cameron's Group at pbs@camerons.net

Once registered, your online account will allow you to order PBS stationery relevant to your approval.

Efficient Funding of Chemotherapy (EFC) arrangements

Should you wish to claim eligible EFC items you will need to obtain a Compounder ID for your pharmacy or the ID of the compounder used to prepare these medicines. More information on how to obtain a Compounder ID can be found at www.pbs.gov.au/ccps.

If you have any enquiries regarding this Ministerial approval, please call 1800 316 389 or email 90Apharmacy@health.gov.au.

Yours sincerely

s47E(c), s47F



Harry Rothenfluh PhD
Delegate of the Secretary of the Department of Health
6 March 2020

Attachments

Certificate of Approval

National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017

Notification of bank account details for approved pharmacist form

Authority to authorise pharmacist(s) to sign claim forms on behalf of approved pharmacist(s) form

Released under the Freedom of Information Act 1982 by the Department of Health, Disability and Ageing



Approval to Supply Pharmaceutical Benefits

National Health Act 1953

s38

with approval number: s38

trading as

s38

has approval to supply pharmaceutical benefits at the premises situated at

s38

effective from the **1st of March** in the year **2020**.

s47F

Delegate, Department of Health

6 March 2020

Date

From: [90Apharmacy](#)
To: s47F
Subject: Statement of Reasons - DP272 - s38 [SEC=OFFICIAL]
Date: Monday, 30 March 2020 9:23:19 AM
Attachments: [image001.png](#)
[SoR - covering letter - DP272 - s38 .pdf](#)
[SoR - Signed SoR and Att A - 24 March 2020.pdf](#)

Dear Ms s47F

Please find attached correspondence in relation to a request by another pharmacist for approval to supply PBS medicines at premises in Sunbury, VIC.

Regards,

s47E(c),
s47F

Ministerial Discretion
Pharmacy Approvals Section
Compliance Systems Branch
Australian Government Department of Health
T: 1800 316 389 | E: 90Apharmacy@health.gov.au
MDP 659, PO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

Released under the Freedom of Information Act 1982 by the Department of Health, Disability and Ageing

Our ref: DP272/E20-119707

s47F
s38

s47F

Request for Ministerial Discretion – s38

Thank you for your email dated 11 March 2020, requesting a Statement of Reasons on behalf of your client, s47F, under subsection 13(1) of the *Administrative Decisions (Judicial Review) Act 1977*, in relation to the decision made by the Minister for Health, the Hon Greg Hunt MP, on 1 March 2020, to approve a pharmacist to supply pharmaceutical benefits at s38 (the proposed premises).

Please find the Statement of Reasons attached. The Statement of Reasons sets out the findings on the material questions of fact, referring to the evidence or other material on which those findings were based, but does not include any information which must not be divulged under section 135A of the *National Health Act 1953*.

Yours sincerely

s47E(c), s47F

Assistant Director
Pharmacy Approvals Section
Provider Benefits Integrity Division
27 March 2020

Encl



The Hon Greg Hunt MP
Minister for Health

Statement of Reasons

This statement is provided in response to a request made by s38

s38 received 11 March 2020, for a Statement of Reasons under section 13 of the *Administrative Decisions (Judicial Review) Act 1977*.

This statement is made in relation to a decision (the Decision) I made on 1 March 2020 under section 90A(2) of the *National Health Act 1953* (the Act) to exercise my discretion to approve a pharmacist to supply Pharmaceutical Benefits Schedule (PBS) medicines at s38

Definitions

In this statement:

'the Act' means the *National Health Act 1953*;

'the Applicant' means the pharmacist who applied: for approval under section 90 of the Act; and for me to exercise my discretion under section 90A of the Act;

'the section 90 Application' means the application made on 4 April 2019 under section 90 of the Act for approval to supply PBS medicines at the proposed pharmacy;

'the Authority' means the Australian Community Pharmacy Authority established under section 99J of the Act;

'the Ministerial Submission' means Ministerial Submission MS19-001851, dated 23 January 2020, provided by my Department in relation to the request for approval by the Applicant made under section 90A of the Act;

'the proposed pharmacy' means premises located at s38

'the Location Rules' means the *National Health (Australian Community Pharmacy Authority Rules) Determination 2018 (PB 46 of 2018)* made under section 99L of the Act;

'the Secretary' means the Secretary of the Department of Health;

'PBS medicines' means Pharmaceutical Benefits Schedule medicines supplied in accordance with the Act.

Released under the Freedom of Information Act 1982 by the Department of Health, Disability and Ageing

Background

1. On 4 April 2019, the Applicant made an application under section 90 of the Act to supply PBS medicines at the proposed pharmacy.
2. In accordance with subsection 90A(3A) of the Act, the section 90 application was referred to the Authority for consideration in accordance with the Location Rules.
3. On 26 July 2019, the Authority recommended to a delegate of the Secretary that the Applicant's section 90 application not be approved because it was not satisfied that the application met the requirements of s38 [REDACTED] the Location Rules.
4. On 20 August 2019, the Secretary's delegate rejected the application. That was in accordance with section 90(3B) of the Act, as the Authority had recommended that the application not be approved.

Request for exercise of discretion

5. On 26 September 2019, my Department received a request from the Applicant for the exercise of my discretion to approve the Applicant to supply PBS medicines at the proposed pharmacy.

s38 [REDACTED]

Decision to exercise discretion

10. On 1 March 2020, I decided, in accordance with subsection 90A(2) of the Act, to exercise my discretion to approve the Applicant's request to supply PBS medicines at the proposed pharmacy.

s38

Evidence taken into account

12. In considering the exercise of my discretion and making my decision, I read and took into account the contents of the Ministerial Submission and the contents of the documents attached to the Ministerial Submission described below:

- Attachment 1: Summary of Ministerial Discretion process and Location Rules

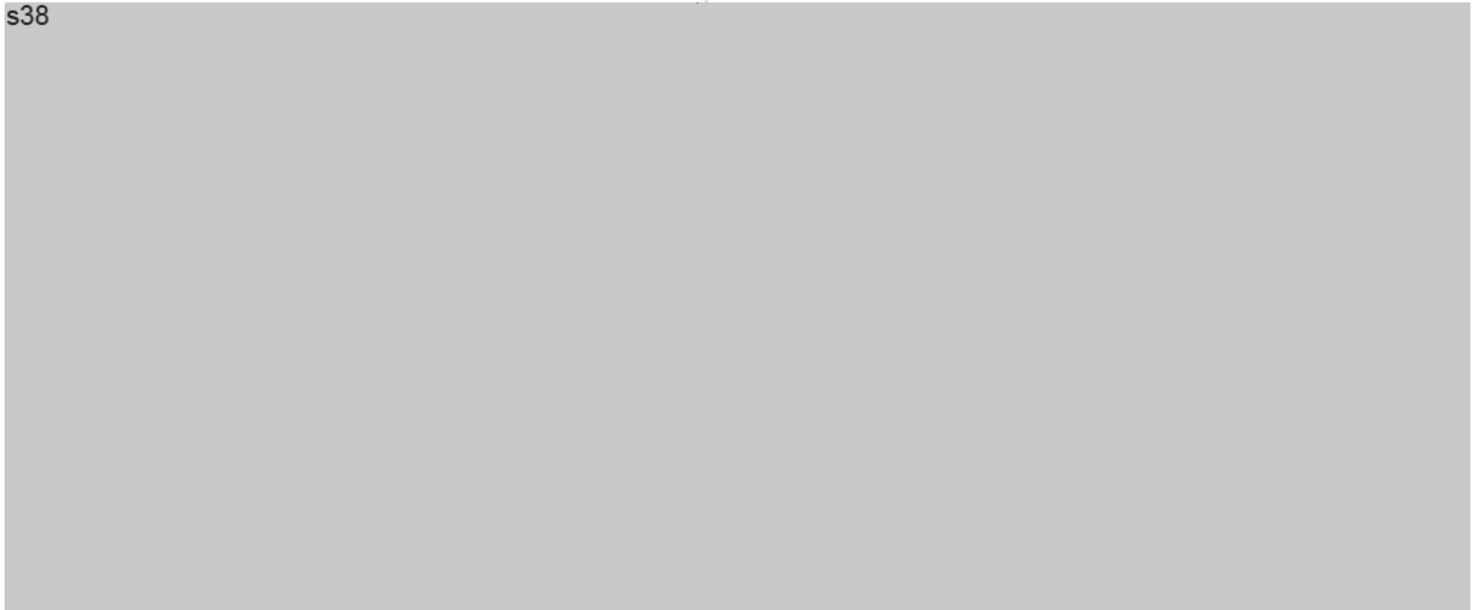
s38

- Attachment 6: Department's research
- Attachment 7: Map of proposed pharmacy and surrounding pharmacies, medical centres and supermarkets

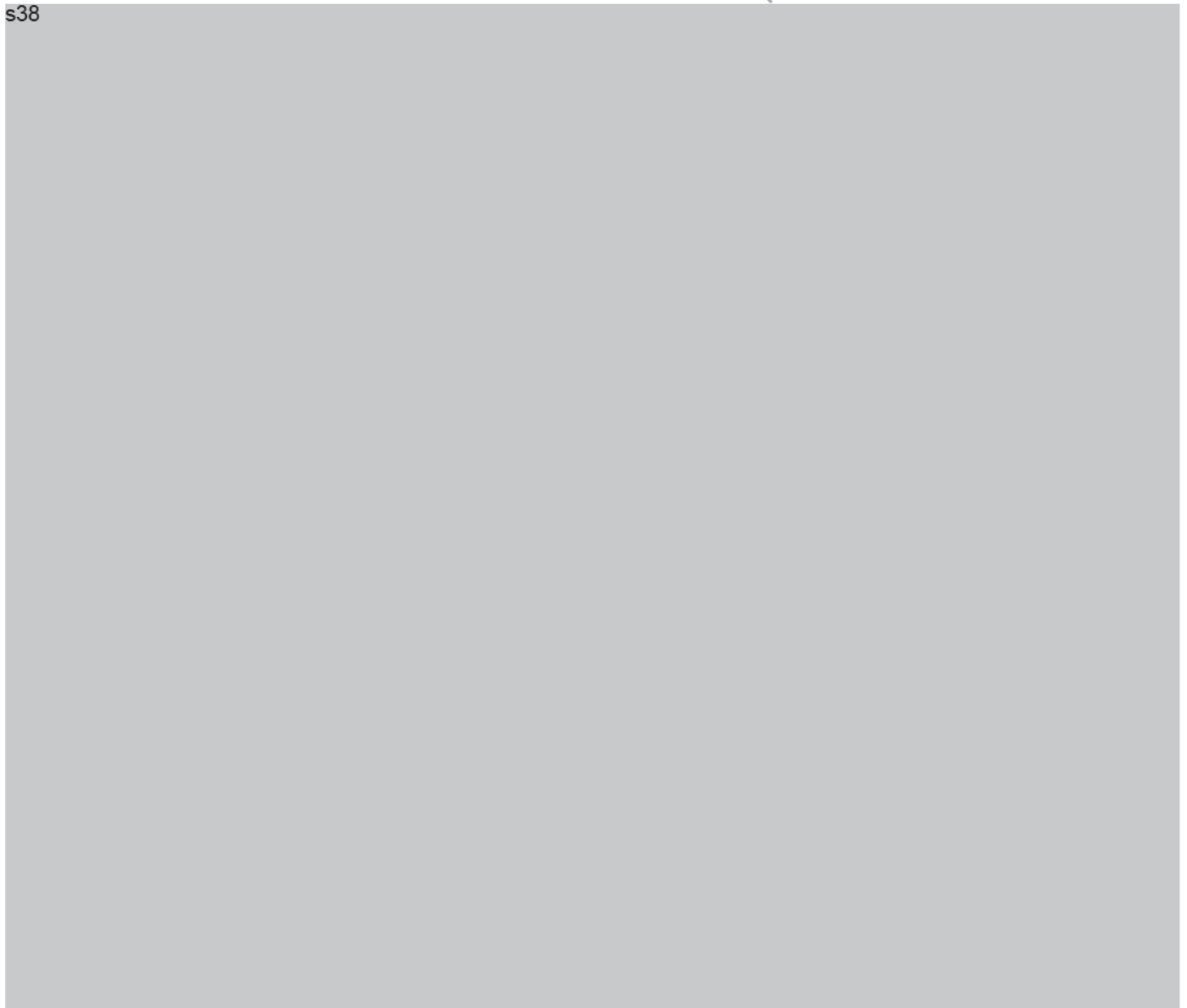
Submissions by the Applicant

13. The Applicant's submissions as to why approval should be granted were set out in the request dated 26 September 2019. In summary, the Applicant submitted:

s38

s38
**Findings on material questions of fact**

22. Based on the information before me, I make the following findings of material facts:

s38


s38

Reasons for decision

23. In making my decision, I was satisfied that the criteria for the exercise of my discretion are met.
24. Specifically, I was satisfied that:
- The Secretary's decision to not approve the Applicant would result in a community being left without reasonable access to PBS medicines supplied by an approved pharmacist (s 90A(2)(a) of the Act); and
 - It was in the public interest to approve the Applicant (s 90A(2)(b) of the Act).

Whether a community will be left without reasonable access

Community

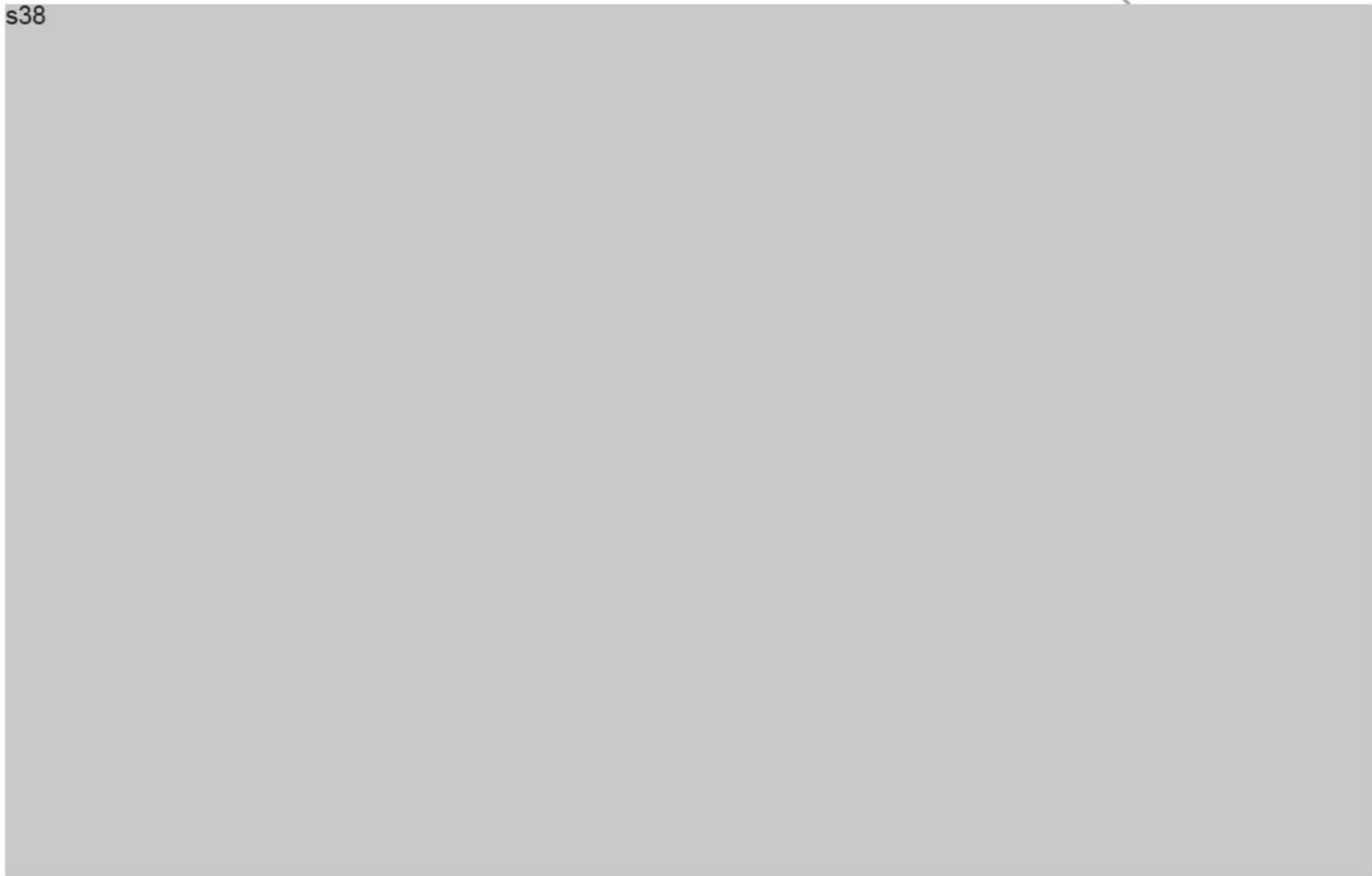
25. I acknowledge that whether a community has reasonable access to PBS medicines will depend on the particular facts and circumstances of the proposal under my consideration. Having regard to the information and submissions provided by the Department, the Applicant ^{s47F} [REDACTED] I formed the view that there is a relevant community that would be affected by the proposed pharmacy not being approved. That community is the residents

s38

26. I reached this view on the basis that:

s38
Reasonable access to PBS medicines

27. I considered whether the decision not to grant approval to the Applicant would leave this community without reasonable access to PBS medicines.

s38


31. In all of the circumstances described above, I found that a decision not to approve the proposed pharmacy would result in the community being left without reasonable access to PBS medicines.

Public interest

32. In making my decision, I took into account the fact that granting approval

s38


33. I found that there is a public interest in the community having access to PBS medicines in the proposed location,^{s38}

s38

s38

I considered that the pharmacy is in a location that will allow convenient access to PBS medicines for the community.

s38

35. On balance, I found that it was in the public interest, under subsection 90A(2)(b), to approve the Applicant.



Greg Hunt

24 MAR 2020

Encl: Attachment A: Extract of the relevant legislation

Released under the Freedom of Information Act 1982 by the Department of Health, 21

ATTACHMENT ANational Health Act 1953

Sections 90A and 90B of the Act provide as follows:

90A Minister may substitute decision approving pharmacist

- (1) This section applies in relation to a decision of the Secretary under section 90 rejecting an application by a pharmacist for approval to supply pharmaceutical benefits at particular premises, if:
 - (a) the application was made on or after 1 July 2006; and
 - (b) the decision was made on the basis that the application did not comply with the requirements of the relevant rules determined by the Minister under section 99L.
- (2) The Minister may substitute for the Secretary's decision a decision approving the pharmacist for the purpose of supplying pharmaceutical benefits at the particular premises if the Minister is satisfied that:
 - (a) the Secretary's decision will result in a community being left without reasonable access to pharmaceutical benefits supplied by an approved pharmacist; and
 - (b) it is in the public interest to approve the pharmacist.
- (3) For the purposes of subsection (2):

community means a group of people that, in the opinion of the Minister, constitutes a community.

reasonable access, in relation to pharmaceutical benefits supplied by an approved pharmacist, means access that, in the opinion of the Minister, is reasonable.
- (4) The power under subsection (2) may only be exercised:
 - (a) on request by the pharmacist made under section 90B; and
 - (b) by the Minister personally.
- (5) Subject to subsection 90B(5), the Minister does not have a duty to consider whether to exercise the power under subsection (2) in respect of the Secretary's decision.
- (6) The power under subsection (2) does not authorise the Minister to approve a pharmacist for the purpose of supplying pharmaceutical benefits at particular premises at which the pharmacist is not permitted, under the law of the State or Territory in which the premises are situated, to carry on business.
- (7) A decision by the Minister not to exercise the power under subsection (2) in

respect of the Secretary's decision does not prevent the pharmacist from making an application to the Administrative Appeals Tribunal under subsection 105AB(7) for review of the Secretary's decision.

(8) For the purposes of this section (other than subsection (7)):

- (a) a reference to a decision of the Secretary includes a reference to a decision of the Secretary that has been affirmed by a decision of the Administrative Appeals Tribunal or an order of a federal court; and
- (b) a reference to a decision of the Administrative Appeals Tribunal includes a reference to a decision of the Administrative Appeals Tribunal that has been affirmed by an order of a federal court.

90B Request to Minister to approve pharmacist

- (1) If section 90A applies to a decision of the Secretary under section 90 rejecting an application by a pharmacist, the pharmacist may, in writing, request the Minister to exercise the Minister's power under subsection 90A(2) in respect of the Secretary's decision.
- (2) The Minister may determine the form in which a request under subsection (1) must be made and, if the Minister does so, such a request must be made in that form.
- (3) A request under subsection (1) must be made:
 - (a) within 30 days after the pharmacist is notified of the Secretary's decision; or
 - (b) if the pharmacist has applied to the Administrative Appeals Tribunal for review of the Secretary's decision—within 30 days after:
 - (i) the pharmacist is given a copy of the Administrative Appeals Tribunal's decision affirming the Secretary's decision; or
 - (ii) the application has been discontinued, withdrawn or dismissed; or
 - (c) if the pharmacist has sought an order from a federal court in respect of the Secretary's decision or a decision of the Administrative Appeals Tribunal affirming the Secretary's decision—within 30 days after:
 - (i) the court has made an order affirming the Secretary's decision or the Administrative Appeals Tribunal's decision, as the case requires; or
 - (ii) the court proceeding has been discontinued, withdrawn or dismissed.
- (4) The Minister must, within 3 months after receiving a request under subsection (1), personally decide whether to consider the request. If the Minister has not made a decision within this period, the Minister is taken to have decided not to consider the request.
- (5) If the Minister decides to consider a request under subsection (1), the Minister

must, within 3 months after making that decision, personally decide whether to exercise the power under subsection 90A(2) in respect of the Secretary's decision. If the Minister has not made a decision within this period, the Minister is taken to have decided not to exercise the power under subsection 90A(2) in respect of the Secretary's decision.

- (6) The Secretary must, by notice in writing, advise the pharmacist of:
- (a) the decision made, or taken to have been made, by the Minister under subsection (4); and
 - (b) if applicable, the decision made, or taken to have been made, by the Minister under subsection (5).

Released under the Freedom of Information Act 1982 by the Department of Health, Disability and Ageing

From: [90Apharmacy](#)
To: s47F
Subject: Notice of Minister's decision to approval - s38 (DP222/s38) [SEC=UNCLASSIFIED]
Date: Wednesday, 30 January 2019 11:58:01 AM
Attachments: [Authority to authorise pharmacist\(s\) to sign claim forms on behalf of approved pharmacist\(s\).pdf](#)
[Notification of bank account details for an approved pharmacist.pdf](#)
[image004.png](#)
[DP222 - s38 - Notice of Ministerial Discretion - Approval Granted 1....pdf](#)
[Approval to Supply certificate - s38 .pdf](#)

Dear s47F

Attached is correspondence in relation to your request for the exercise of the Ministers discretionary power in relation to premises in s38

Regards,

s47E(c),
s47F

Assistant Director

Ministerial Discretion

Pharmacy Approvals Section

Compliance Systems Branch

Australian Government Department of Health

T: 11C | E: 90Apharmacy@health.gov.au

MDP 659, PO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present

s38

R



Australian Government
Department of Health

Ref No: DP222

s47F

Dear Ms s47F

Notice of Ministerial decision – approval granted

On 23 August 2018 we received your request under subsection 90A(2) of the *National Health Act 1953* (the Act) for the Minister, the Hon Greg Hunt MP (the Minister), to exercise his discretionary power to approve the supply of pharmaceutical benefits at s38 (the pharmacy premises).

As delegate of the Secretary of the Department of Health under subsection 90B(6) of the Act, I am writing to notify you that on **18 January 2019** the Minister exercised his discretionary power and approved **you** in respect of the pharmacy premises.

The approval number that has been allocated to your approval by the delegate of the Minister under regulation 16 of the *National Health (Pharmaceutical Benefits) Regulations 2017* is s38. Please ensure that you reference this number on all official communications with us and when submitting PBS claims to the Department of Human Services.

We have not been provided with evidence of your Victorian approval to operate a pharmacy business, including the pharmacy trading name, at the address in respect of which approval has been granted.

Your approval number has therefore been deactivated until **1 March 2019**.

Once we receive evidence of your approval to operate a pharmacy under Victorian law, your approval will be re-activated.

Enclosed is your 'Certificate of Approval' in respect of the above premises.

Conditions of approval

It is important to note that this approval is subject to the conditions specified in section 92A of the Act, including those determined by the Minister under subsection 92A(1)(f) of the Act (refer to *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017* attached).

As your application was made under Item 136 of the National Health (Australian Community Pharmacy Authority Rules) Determination 2018 (the Pharmacy Location Rules), it is subject to the restrictions applicable to that Item (see Item 316 of the Pharmacy Location Rules).

As the approved pharmacist, it is your responsibility to:

- understand and comply with any changes to the legislation in the supply of Pharmaceutical Benefits;
- let us know of any changes that affect the supply of Pharmaceutical Benefits Scheme (PBS) medicines at the pharmacy premises; and
- notify us if changes occur to your pharmacy premises and/or the approved pharmacist/s.

Provision of bank account for PBS payments and authorising pharmacist(s) to submit claims

You will need to complete the following forms (attached) to enable payment of your PBS claims and/or to authorise a pharmacist to sign claim on your behalf:

- *Notification of bank account details for approved community pharmacist*
- *Authority to authorise pharmacist(s) to sign claim forms on behalf of approved pharmacist(s)*

These forms must be returned to pbsapprovesuppliers@health.gov.au for processing.

Pharmacy landline phone number

As you have advised that the pharmacy is open and trading, you will need to advise us of the pharmacy's landline by emailing us at pbsapprovesuppliers@health.gov.au.

Online claiming of PBS

You will also need to liaise with the Department of Human Services to arrange for a PKI certificate to be issued to enable you to submit PBS claims online. To make a claim for reimbursement the following forms must be submitted to the Department of Human Services:

- *Online claiming for Pharmaceutical Benefits Scheme – Application and terms of conditions; and*
- *Notification of Australian Business Number and reference identification for tax treatment purposes and Recipient Created Tax Invoice agreement.*