



Australian Government

Department of Health and Aged Care

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 **23rd day of May in the year 2023**

s47F

Signature

Delegate, Department of Health and Aged Care

26 May 2023

Date

From: [90Apharmacy](#)
To: s47F
Cc: [90Apharmacy](#)
Subject: Notice of decision - Request for Ministerial discretion - s38 [SEC=OFFICIAL]
Date: Friday, 6 January 2023 9:57:39 AM
Attachments: [image001.png](#)
[Notice of Ministers decision to approve - s38 .pdf](#)
[s38 - Approval to Supply certificate - s38 .pdf](#)
[Conditions of approval.pdf](#)
[health03pbs-202209 - Authority to permit person\(s\) to enquire and/or sign claim forms on behalf of approved pharmacist\(s\).PDF](#)
[health05pbs-202209 - Notification of bank account details for an approved pharmacy.PDF](#)

Good morning Mr s47F

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

including:

- Notice of Minister's decision to approve - s38
- PBS Approval to Supply Certificate
- National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017

Please complete and return the following documents 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(o),
s47F

Ministerial Discretion Team
Provider Support and Systems Branch

Benefits Integrity and Digital Health Division, Health Resourcing Group
 Australian Government, Department of Health and Aged Care
 E: 90Apharmacy@health.gov.au
 PO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care 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 and Aged Care

Ref: DP369

s47F

s47F

Dear Applicant

Notice of Approval

I, Lynda Foyster, delegate of the Secretary of the Department of Health and Aged Care (department) for subsection 90B(6) of the *National Health Act 1953* (Act), am writing to notify you that on **28 December 2022**, the Minister for Health and Aged Care (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 for 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.

We have not been provided with evidence of approval from the relevant state or territory pharmacy authority to operate a pharmacy business at the address in respect of which approval has been granted.

Your approval number has therefore been deactivated until **8 February 2023**.

Once we receive evidence that the relevant state or territory pharmacy authority has granted you approval to operate a pharmacy business at the approved premises, your approval will be re-activated. Please email this evidence to 90Apharmacy@health.gov.au.

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* (Pharmacy Location Rules), it is subject to the restrictions applicable to that Item. Specifically, the pharmacy is restricted from relocating from outside of the s38, for a period of ten years from

28 December 2022, unless there are exceptional circumstances (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
- 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 uploaded, by a signed in user, to the PBS Approved Suppliers Portal accessible at <https://pbsapprovesuppliers.health.gov.au>

Pharmacy landline

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

Online claiming for PBS

If you have not already done so, you must register your ABN and enter into a Recipient Created Tax Invoice Agreement with Services Australia (Medicare) for your new pharmacy approval number.

You will need to set-up in PRODA for PBS online claiming, including registering your organisation in PRODA, adding and linking to PBS Online with your new pharmacy approval number, and registering a B2B Device for claiming.

Information about online claiming, PRODA set-up and the required forms are available from Services Australia website at www.servicesaustralia.gov.au using the search term 'PBS online claiming'.

Ordering PBS stationery supplies

PBS stationery must be ordered through Health Professional Online Services (HPOS). To set up a HPOS account, you must:

- register for an individual PRODA account (employees should also register for an individual PRODA account if they don't yet have one)
- register your pharmacy as an organisation in PRODA
- link to the HPOS service in PRODA using the pharmacy approval number (administration number)

Please refer to the guide for ordering PBS stationery through HPOS available at servicesaustralia.gov.au/pbsstationery for further information.

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 questions, please email 90Apharmacy@health.gov.au.

Yours sincerely

s47E(c), s47F



Lynda Foyster
 Delegate of the Secretary of the Department of Health and Aged Care
 6 January 2023

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 and Aged Care

Approval to Supply Pharmaceutical Benefits

National Health Act 1953

Health, Disability and Ageing

s38

with approval number: s38
trading as:

s38

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

s38

effective from the **28th day of December in the year 2022**

s47F

6 January 2023

Delegate

Date

Department of Health and Aged Care

From: [90Apharmacy](#)
To: s47F
Subject: Request for Statement of Reasons - s38 [SEC=OFFICIAL]
Date: Thursday, 9 February 2023 10:43:02 AM
Attachments: [image001.png](#)
[Signed SoR and Att A.pdf](#)
[SoR Cover letter to third party - DP369 - s38 .pdf](#)

Dear Mr s47F

Please find attached the covering letter and signed Statement of Reasons in relation to your client's request regarding the approval of premises in s38 to supply pharmaceutical benefits.

Regards

s47E(c),
s47F

Ministerial Discretion Team
Provider Support and Systems Branch

Benefits Integrity and Digital Health Division | Health Resourcing Group
 Australian Government, Department of Health and Aged Care
 E: 90Apharmacy@health.gov.au
 PO Box 9848, Canberra ACT 2601, Australia

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



The Hon Mark Butler MP
Minister for Health and Aged Care

Statement of Reasons

This statement is provided in response to a request received on 11 January 2023 from s38

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 the 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

s38

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 subsequently under subsection 90B(1) for the exercise of the Minister for Health and Aged Care's discretion under subsection 90A(2) of the Act;

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

'department' means the Australian Government Department of Health and Aged Care;

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

'Minister' means the Minister for Health and Aged Care;

'Ministerial Submission' means the Ministerial Submission provided by my department on 14 December 2022, 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

'Secretary' means the Secretary of the department;

'section 90 Application' means the application made on 17 March 2022 under section 90 of the Act for approval to supply pharmaceutical benefits at the proposed premises.

Background

1. On 17 March 2022, the Applicant made the section 90 Application to the Secretary to supply pharmaceutical benefits at the proposed premises.
2. Consistent 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 April 2022, 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 requirements of s38
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 9 June 2022, 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 or delegate under section 90 with an approval decision.

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Exercise of discretionary power

14. On 28 December 2022, I decided, in accordance with subsection 90A(2) of the Act, to approve the Applicant's request to supply pharmaceutical benefits at the proposed premises.
15. In a letter dated 6 January 2023, Ms Lynda Foyster, A/g Assistant Secretary, Provider Support and Systems Branch of my department, notified the Applicant of my decision to approve the request.

s38

18. An extract of the relevant legislation is at **Attachment A**.

Evidence taken into account

19. 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 13.

Submissions by the Applicant

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Findings on material questions of fact

24. Based on the material before me, including my department's research, I made the following findings of material facts:

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My Decision

25. I decided to approve the Applicant's request for approval to supply pharmaceutical benefits at s38

Reasons for decision

26. I decided to approve the Applicant's request because I was satisfied the criteria for the exercise of my discretion were met. Specifically, I was satisfied:
- 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

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

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Reasonable access and public interest

29. I considered that, having regard to the information and submissions provided by the Applicant, third parties and my department, it was in the public interest to approve the Applicant's request.

s38

32. Accordingly, I decided to approve the Applicant's request because I was satisfied it met the criteria in subsection 90A(2) of the Act.



Mark Butler

7 February 2023

Encl: Attachment A: Extract of the relevant legislation

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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



Australian Government
Department of Health and Aged Care

Ref: DP369

s38

s47F

Dear Pharmacist

Request for Ministerial Approval – s38

I refer to a request made on your behalf on 11 January 2023 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 on 28 December 2022 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*.

Yours sincerely

s47E(c), s47F

A/g Assistant Director
 PBS Approved Suppliers Section
 Benefits Integrity and Digital Health Division
 9 February 2023

Encl: Statement of Reasons

From: [90Apharmacy](#)
To: s47F
Subject: Notice of decision - Request for Ministerial discretion - DP358 - s38 [SEC=OFFICIAL]
Date: Tuesday, 27 September 2022 9:17:08 AM
Attachments: [image001.png](#)
[Authority to permit person\(s\) to enquire and-or sign claim forms on behalf of pharmacist\(s\).PDF](#)
[Conditions of approval.PDF](#)
[Notification of bank account details for an approved pharmacy form.PDF](#)
[s38 - Approval to Supply certificate - s38.pdf](#)
[DP358 - Notice of Approval - s38.pdf](#)

Good morning Mr s47F

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

including:

- Notice of Minister's decision to approve – s38
- PBS Approval to Supply Certificate
- National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2017

Please complete and return the following documents (attached) 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

Ministerial Discretion Team
Provider Support and Systems Branch

Benefits Integrity and Digital Health Division | Health Resourcing Group
 Australian Government, Department of Health and Aged Care
 E: 90Apharmacy@health.gov.au
 PO Box 9848, Canberra ACT 2601, Australia

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Australian Government

Department of Health and Aged Care

Our ref: DP358/E22-80417

s38

s47F

Dear Applicant

Notice of Approval

I, Harry Rothenfluh, delegate of the Secretary of the Department of Health and Aged Care for subsection 90B(6) of the *National Health Act 1953* (Act), am writing to notify you that on **11 September 2022**, the Minister for Health and Aged Care, the Hon Mark Butler 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 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 approved premises.

As we do not have evidence the Victorian Pharmacy Board (VPA) has approved you to operate a pharmacy business at the address above, your approval number has been deactivated until **24 October 2022**.

Please email evidence the VPA has approved you to operate a pharmacy business at the approved premises to 90Apharmacy@health.gov.au. Once the delegate is satisfied all requirements have been met, the approval will be re-activated.

Conditions of approval

It is important to note 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 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.

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 at www.pbsapprovedsuppliers.health.gov.au

Pharmacy landline

Once 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 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 queries 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 and Aged Care
 26 September 2022

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 and Aged Care

Approval to Supply Pharmaceutical Benefits

National Health Act 1953

s38

with approval number: s38

trading as:

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

s38

effective from the **11th day of September in the year 2022**

s47F

26 September 2022

Delegate

Date

Department of Health and Aged Care

From: [90Apharmacy](#)
To: s47F
Subject: Request for Ministerial Discretion - DP356 - s38 [SEC=OFFICIAL]
Date: Tuesday, 30 August 2022 10:25:45 AM
Attachments: [image001.png](#)
[Notice of Minister s decision to approve - s38 .pdf](#)
[Authority to permit person\(s\) to enquire and-or sign claim forms on behalf of pharmacist\(s\).PDF](#)
[Notification of bank account details for an approved pharmacy form.PDF](#)
[Conditions of approval.PDF](#)

Dear s47F

Please find attached correspondence relating to your client's request to supply Pharmaceutical Benefits Scheme (PBS) medicines s38. As outlined in the attached Notice of Approval, please note this approval is conditional on the relocation of the existing approved premises and cancellation of the associated approval at the existing premises.

Please complete and return the following forms (attached) 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

Ministerial Discretion Team
Provider Support and Systems Branch

Benefits Integrity and Digital Health Division | Health Resourcing Group
 Australian Government, Department of Health and Aged Care
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Released under the Freedom of Information Act 1982 by the Department of Health, Disability and Ageing



Australian Government

Department of Health and Aged Care

Our ref: DP356/E22-68681

s38

s47F

Dear Applicant

Notice of Approval

I, Harry Rothenfluh, delegate of the Secretary of the Department of Health and Aged Care, for subsection 90B(6) of the *National Health Act 1953* (Act), am writing to notify you that on **22 August 2022**, the Minister for Health and Aged Care, the Hon Mark Butler MP (Minister), approved

s38

to supply pharmaceutical benefits at

s38

s38

You are also required to provide evidence of your approval from the Victorian Pharmacy Authority to operate a pharmacy business at the approved premises.

s38

s38

Approval at the approved premises

A delegate of the Minister for regulation 16 of the *National Health (Pharmaceutical Benefits) Regulations 2017* has issued administration number s38, which will become the approval number in respect of the approved premises s38

Prior to 4:00 pm (Canberra time) on the day of opening, you must email 90Apharmacy@health.gov.au to confirm the pharmacy is open and trading at the new premises. Internal and external photographs of the premises, including the dispensary area and pharmacy trading name signage, must be provided as evidence.

Once the delegate is satisfied all requirements have been met, the approval will be activated and the approved pharmacist(s) can submit claims for PBS medicines supplied that day using the new approval number. Please note, an approval to supply PBS medicines is not proprietary in nature and should not be used as security against a loan.

Please do not make a request for your PBS Certificate as this will be emailed to you for your records once the approval has been activated.

Conditions of approval

It is important to note this approval will be 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* (Pharmacy Location Rules), it is subject to the restrictions applicable to that Item (see Item 313 of the Pharmacy Location Rules). Any subsequent application to relocate the pharmacy must be made in accordance with the Pharmacy Location Rules in force at the time the application is made.

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 at the pharmacy premises
- notify us if changes occur to your pharmacy premises and/or the approved pharmacist/s.

Bank account for PBS payments and authorising pharmacist(s) to submit claims

You will need to complete the following forms (attached) in respect of the approved premises, to enable payment of your claims for supplies of pharmaceutical benefits 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 submitted via the PBS Approved Suppliers Portal at www.pbsapprovedsuppliers.health.gov.au

Pharmacy landline

When the pharmacy is open and trading, please email the pharmacy's landline to 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 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.

Please **email the anticipated opening date** of the pharmacy at the approved premises to 90Apharmacy@health.gov.au. Any questions regarding this letter may also be emailed to this address.

Yours sincerely

s47E(c), s47F

Harry Rothenfluh

Delegate of the Secretary of the Department of Health and Aged Care

29 August 2022

Attachments

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

From: [90Apharmacy](#)
To: s47F
Subject: Request for ministerial discretion - s38 [SEC=OFFICIAL]
Date: Friday, 20 May 2022 9:23:49 AM
Attachments: [image001.png](#)
[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](#)
[Notice of Minister's decision to approve - s38 .pdf](#)
[s38 - Approval to Supply certificate.pdf](#)

Good morning Mr s47F

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

- Notice of Minister's decision to approve – s38
- PBS Approval to Supply Certificate
- 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



Australian Government

Department of Health

Our ref: DP353/E21-626639

Your ref: ATC:HM:147397-14

s38

s47F

Dear Director/s

Notice of Approval

I, Kim DeLacy, delegate of the Secretary of the Department of Health for subsection 90B(6) of the *National Health Act 1953* (Act), am writing to notify you that on **17 May 2022**, the Minister for Health and Aged Care, the Hon Greg Hunt MP (Minister), approved:

s38

to supply pharmaceutical benefits 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 claims for supplies of pharmaceutical benefits (medicines subsidised under the Pharmaceutical Benefits Scheme (PBS)) to Services Australia.

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

As we have not been provided with evidence of your approval from the Victorian Pharmacy Authority to operate a pharmacy business at the premises in respect of which approval has been granted, your approval has been deactivated until Monday **27 June 2022**.

Once we receive evidence that the Board has granted you approval to operate a pharmacy business at the approved premises, and you have confirmed that the pharmacy is open and trading, your approval will be re-activated. Please email this evidence to 90Apharmacy@health.gov.au

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 (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 at the pharmacy premises
- 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 claims for supplies of pharmaceutical benefits 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.pbsapprovesuppliers.health.gov.au

Pharmacy landline

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

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

Kim DeLacy
 Delegate of the Secretary of the Department of Health
 19 May 2022

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 **17th day of May in the year 2022**

s47F

19 May 2022

Signature

Date

Delegate, Department of Health

From: [90Apharmacy](#)
To: s47F
Cc: [90Apharmacy](#)
Subject: Statement of Reasons - s38 [SEC=OFFICIAL]
Date: Monday, 20 June 2022 8:28:48 AM
Attachments: [image001.png](#)
[SoR Cover letter to third party - s38 .pdf](#)
[Signed SoR and Att A.PDF](#)

Dear s47F

Please find attached the covering letter and Statement of Reasons in relation to your client's request for approval at premises in s38 .

Kind regards

s47E(c),
s47F

Ministerial Discretion Team
PBS Approved Suppliers Section

Benefits Integrity and Digital Health Division | Health Resourcing 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

Our ref: DP353/ E22-140101

s38

s47F

Dear Pharmacy Owner

Request for Ministerial Approval – s38

I refer to a request made on your behalf on 24 May 2022, 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 on 17 May 2022, to exercise discretion to approve the 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*.

Yours sincerely

s47E(c), s47F

Assistant Director
PBS Approved Suppliers Section
Benefits Integrity and Digital Health Division
17 June 2022

Encl:



The Hon Mark Butler MP
Minister for Health and Aged Care

Statement of Reasons

This statement is provided in response to a request received on 24 May 2022 from

s38

s38

, 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 the former 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 subsequently under subsection 90B(1) for the exercise of the Minister for Health and Aged Care's discretion under subsection 90A(2) of the Act;

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

'Department' means the Australian Government Department of Health;

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

'Minister' means the Minister for Health and Aged Care;

'Ministerial Submission' means Ministerial Submission MS22-000418, provided by the Department on 16 May 2022, 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;

'section 90 Application' means the application made by the Applicant on 9 September 2021 under section 90 of the Act for approval to supply pharmaceutical benefits at the proposed premises.

Background

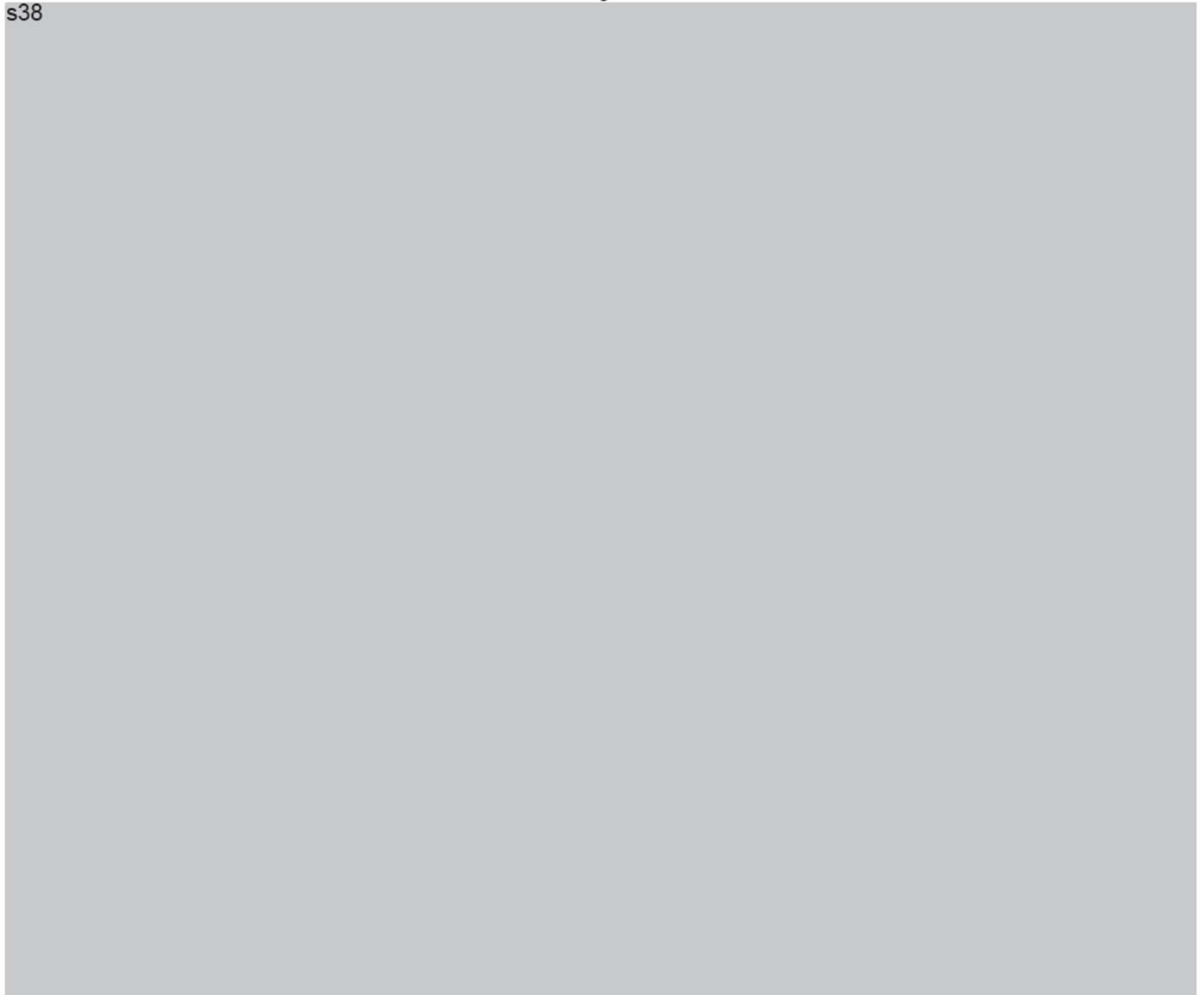
1. On 9 September 2021, the Applicant made the section 90 Application to the Secretary.
2. Consistent with subsection 90(3A) of the Act, the section 90 Application was referred to the Authority for consideration in accordance with the Location Rules.
3. On 8 October 2021, the Authority recommended to 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 November 2022, 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 the Department that the Minister exercise their discretionary power under subsection 90A(2) of the Act. Subsection 90A(2) of the Act provides that the Minister may, in certain circumstances, substitute a rejection by the Secretary or delegate under section 90 with an approval decision.

s38

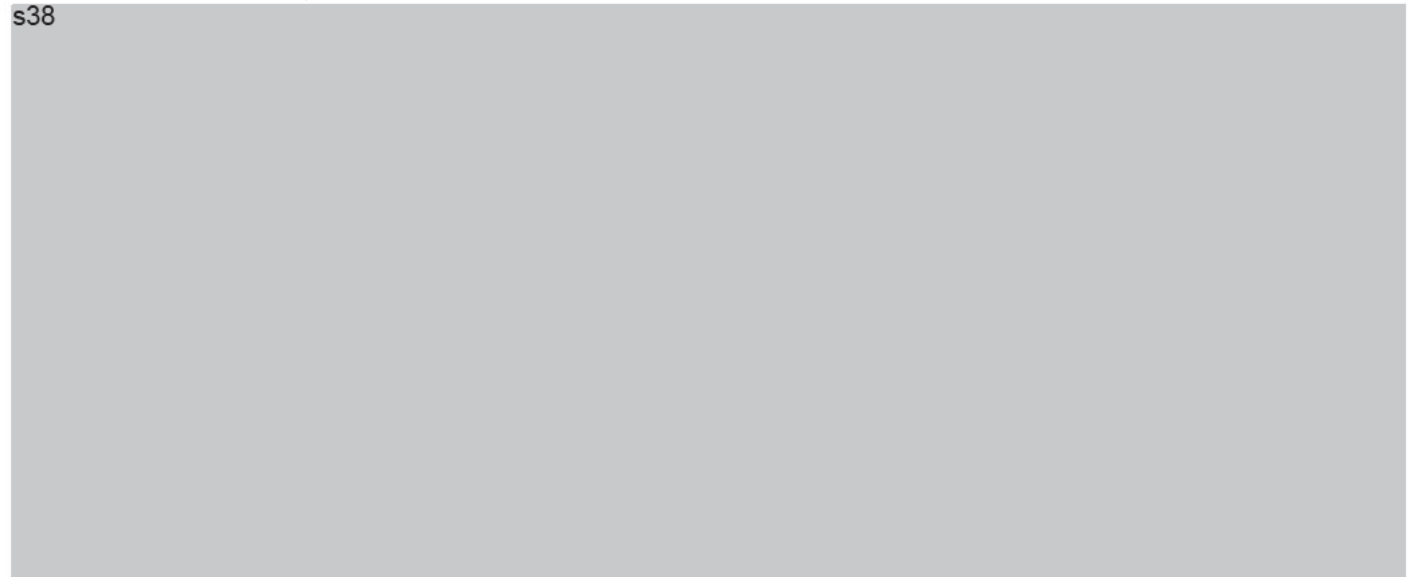
s38

**Evidence taken into account**

20. In considering the exercise of the Minister's discretion and making the decision, the former Minister took into account the contents of the Ministerial Submission and the contents of the documents attached to the Ministerial Submission as outlined at paragraph 14.

Submissions by the Applicant

s38



s38

Correspondences provided by the Applicant relating to the request for approval

22. Correspondence in support of approval of the pharmacy were included with the request for approval and/or sent directly to the Minister's office.
23. The Court has previously found that it is relevant to consider any community support, such as a petition, for the granting of approval, but that such 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.

s38

s38

Findings on material questions of fact

lit

s38

s38

The decision

26. The former Minister decided to approve the Applicant's request to supply pharmaceutical benefits at s38

Reasons for decision

27. The former Minister decided to approve the Applicant's request because they were satisfied that the criteria for the exercise of their discretion were met.

28. Specifically, the former Minister 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

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

30. Having regard to the information and submissions provided by the Applicant, the Department and third parties, the former Minister formed the view that there is a relevant community that would be affected by the proposed pharmacy not being approved. The former Minister considered the relevant community to be the patients attending s38

s38

Reasonable access

31. The former Minister 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

Public interest

33. The former Minister considered that, having regard to the information and submissions provided by the Applicant, the Department and third parties, the public interest favoured the community having convenient access to pharmaceutical benefits at the proposed location.



15 June 2022

Signed pursuant to section 17 of the Administrative Decisions (Judicial Review) Act 1977 by

Mark Butler

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
Subject: Request for ministerial discretion - s38 [SEC=OFFICIAL]
Date: Friday, 17 September 2021 11:41:20 AM
Attachments: [image001.png](#)
[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](#)
[Notice of Minister's decision to approve s38 .pdf](#)
[s38 - Approval to Supply certificate.pdf](#)

Good morning s47F

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

- Notice of Minister's decision to approve – s38
- PBS Approval to Supply Certificate
- *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

Our ref: DP330/E21-27213

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 **13 September 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.

We have not been provided with evidence of your Victorian Pharmacy Board (VPA) approval to operate a pharmacy business at the address in respect of which approval has been granted.

Your approval number has therefore been deactivated until **25 October 2021**.

Once we receive evidence that the VPA has granted you approval to operate a pharmacy business at the approved premises, your approval will be re-activated. Please email this evidence to 90Apharmacy@health.gov.au

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* (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 PBS medicines;
- 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

Once 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
17 September 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 13th day of **September** in the year **2021**

s47F

Signature

Delegate, Department of Health

17 September 2021

Date

From: [90Apharmacy](#)
To: s47F
Subject: Request for a Statement of Reasons - s38
Date: Wednesday, 13 October 2021 9:42:46 AM
Attachments: [image001.png](#)
[SoR Cover letter to third party.pdf](#)
[Signed SoR and Attachment A.pdf](#)

Dear Mr s47F

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

Kind regards

s47E(c),
s47F

Ministerial Discretion Team
PBS Approved Suppliers Section

Benefits Integrity and Digital Health Division | Health Resourcing 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

Our ref: DP330/E21-517306

s47F

s38

s47F

Dear Pharmacy Owner

Request for Ministerial Discretion – s38

I refer to a request made on your behalf on 20 September 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 13 September 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*.

Yours sincerely

s47E(c), s47F

Assistant Director
PBS Approved Suppliers Section
Benefits Integrity and Digital Health Division
13 October 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 received on 20 September 2021 from s38

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 MS21-000819, provided by my Department on 20 August 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

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

'section 90 Application' means the application made by the Applicant on 17 December 2020 under section 90 of the Act for approval to supply pharmaceutical benefits at the proposed premises.

s38

s38

5. 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. As the Authority found that a requirement of s38 of the Location Rules was not met, the Authority recommended to a delegate of the Secretary that the Applicant's section 90 Application not be approved.
6. On 25 February 2021, the Secretary's delegate rejected the section 90 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

7. 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.

s38

s38

Exercise of discretionary power

14. On 13 September 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

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

Evidence taken into account

19. 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 13.

Submissions by the Applicant

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

s38

s38

Correspondences provided by the Applicant relating to the request for approval

s38

I noted that 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.

s38

s38



Findings on material questions of fact

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

s38



s38

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.

27. 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. I considered the relevant community includes ^{s38}

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 these points 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

Public interest

s38

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



Greg Hunt

8 October 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
Cc: [90Apharmacy](#)
Subject: Request for ministerial discretion - s38 [SEC=OFFICIAL]
Date: Wednesday, 14 July 2021 5:01:33 PM
Attachments: [image001.png](#)
[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](#)
[s38 - Approval to Supply certificate.pdf](#)
[Notice of Minister s decision to approve - s38 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

Our ref: DP324/E21-7659

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 **8 July 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.

We have not been provided with evidence of your Victorian Pharmacy Board (VPA) approval to operate a pharmacy business at the address in respect of which approval has been granted.

Your approval number has therefore been deactivated until **28 July 2021**.

Once we receive evidence that the VPA has granted you approval to operate a pharmacy business at the approved premises, your approval will be re-activated. Please email this evidence to 90Apharmacy@health.gov.au

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* (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 PBS medicines;
- 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
14 July 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 8th day of **July** in the year **2021**

s47F

Signature

Delegate, Department of Health

14 July 2021

Date

From: [90Apharmacy](#)
To: s47F
Subject: Request for Statement of Reasons – s38 [SEC=OFFICIAL]
Date: Tuesday, 10 August 2021 10:05:13 AM
Attachments: [image001.png](#)
[SoR Cover letter to third party.pdf](#)
[Signed SoR and Att A - 6 Aug 2021.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



Building a stronger,
 healthier country
 Yesterday
 today and
 tomorrow



Australian Government

Department of Health

Our ref: DP324/E21-125741

Pharmacy Owner

s38

s47F

Dear Pharmacy Owner

Request for Statement of Reasons – s38

I refer to a request made on your behalf on 20 July 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 8 July 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*.

Yours sincerely

s47E(c), s47F

Assistant Director
PBS Approved Suppliers Section
Benefits Integrity and Digital Health Division
10 August 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 received on 20 July 2021 from

s38

s38 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 MS21-000449, provided by my Department on 24 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 9 November 2020 under section 90 of the Act for approval to supply pharmaceutical benefits at the proposed premises.

Background

1. On 9 November 2020, the Applicant made the section 90 application to the Secretary.
2. Consistent 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.

s38

being

Exercise of discretionary power

13. On 8 July 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