

Pharmacy Trial Program (Tranche 1) Grant Guidelines

Targeted non-competitive grants

Department of Health

December 2016

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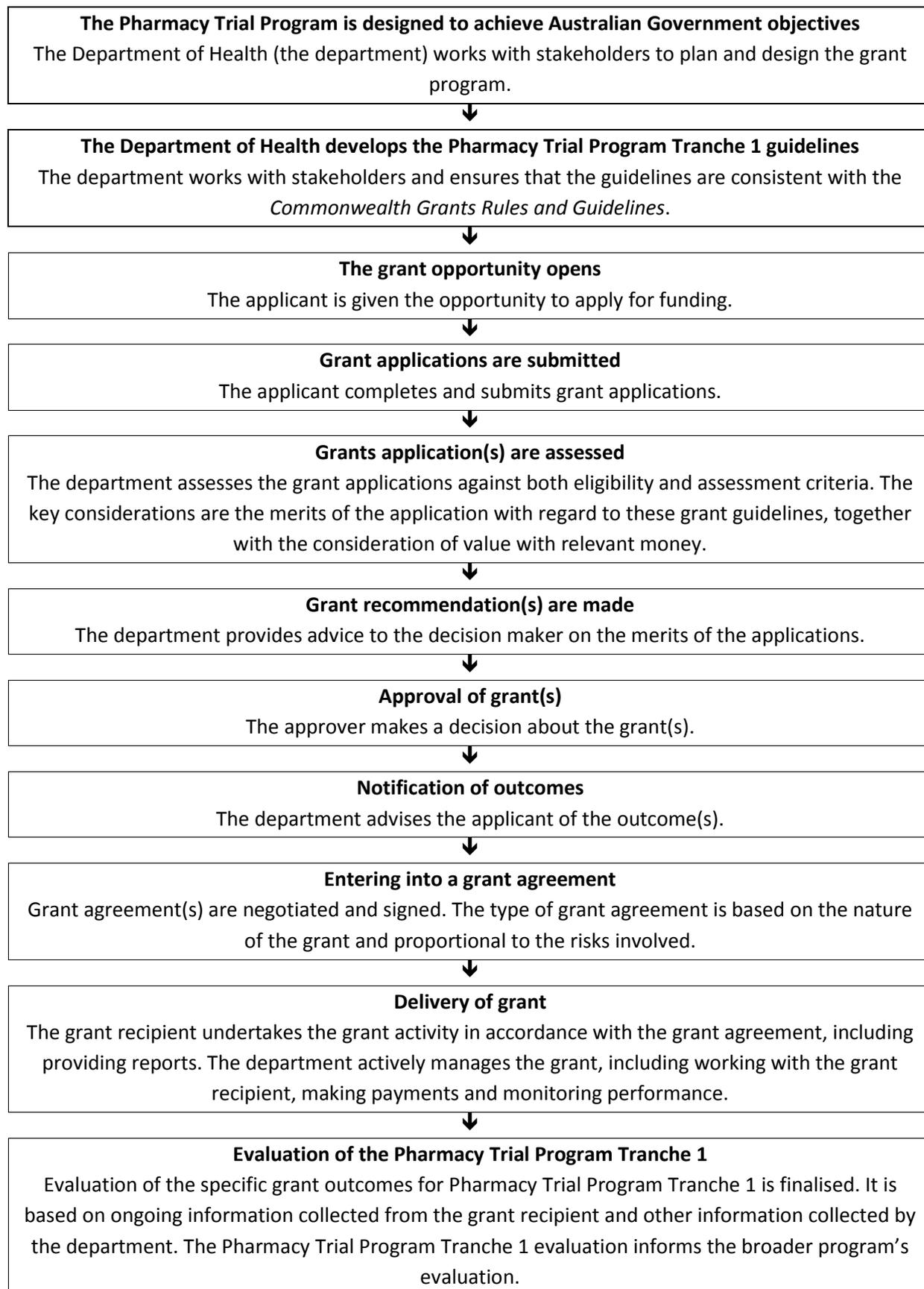
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1. Pharmacy Trial Program Tranche 1



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2. About the grant program

These guidelines contain information for the administration of grants provided under the Australian Government's Pharmacy Trial Program Tranche 1 (PTP Tranche 1).

The Pharmacy Trial Program (PTP) sits under the Sixth Community Pharmacy Agreement (6CPA) and aims to extend the funded roles of pharmacists in the delivery of primary health care services and will trial new and expanded community pharmacy programs which seek to improve clinical outcomes for consumers. The government has opted for a staged approach to the development and delivery of trials under the PTP to allow processes to be developed with stakeholder input and alleviate administrative burden on the sector.

The Australian Government recognises the key role that pharmacists play in the health care team and in improving health outcomes for Australians through activities associated with the quality use of medicines, health promotion, management of chronic disease, risk assessment and early intervention, and broader management of patient health.

Once finalised, the outcomes of the trials will be evaluated by an independent health technology assessment committee to inform decisions about any broader roll-out. It is expected the evaluation will be conducted by the MSAC, unless there is an aspect to the proposed trial that requires consideration by another health technology assessment committee (such as the use of devices or medicines).

2.1 PTP Tranche 1 background

Under the 6CPA, signed on 23 May 2015, \$50 million has been allocated for PTP. PTP will trial new and expanded community pharmacy programs which seek to improve clinical outcomes for consumers by extending the role of pharmacists in the delivery of primary healthcare services through community pharmacy.

Approximately \$10 million over three years has been allocated for PTP Tranche 1. The Government has agreed to fund trials in the following areas:

- Pharmacy based screening and referral for diabetes;
- Improved medication management for Aboriginal and Torres Strait Islanders through pharmacist advice and culturally appropriate services; and
- Improved continuity in the management of patients' medications when they are discharged from hospital.

Trials undertaken under the PTP need to reflect the centrality of community pharmacy within the 6CPA and also as a key point of care for consumers. However, the involvement of pharmacy can potentially take a number of forms, including where the community pharmacy is a participant in a broader care model.

Further funding of \$600 million has been set aside to support recommendations by an independent health technology assessment committee about which new programs/services should continue to be funded after trials conclude, based on assessment of their clinical and cost effectiveness.

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2.2 Program objectives and outcomes

2.2.1 Program Objective

The objective of PTP Tranche 1 is to fund an organisation to work with pharmacies and pharmacists to trial new and expanded community pharmacy programs which seek to improve clinical outcomes for consumers, and/or extend the role of pharmacists in the delivery of primary health care services through community pharmacy.

2.2.2 Program Outcome

The expected outcome of PTP Tranche 1 is to trial activities in community pharmacies that are innovative and cost-effective services, with the potential to be delivered nationally.

2.2.3 Program performance indicators

To assist the department to effectively assess whether PTP Tranche 1 outcomes have been achieved, the organisation will be required to report against performance indicators as set out in their grant funding agreement. The following performance indicators are indicative and will vary according to the objectives of each trial:

- Medication advice, review and management leading to improved medication adherence and compliance, as evidenced, for example, by a reduction in medication-related hospital admissions or re-admissions;
- Risk assessment and advice to patients leading to early detection, intervention and prevention of chronic disease;
- Enhanced collaboration and integration between pharmacists and other primary health care providers; and
- Cost-effective, expanded pathways of service delivery by community pharmacy are identified.

These grants will be undertaken in accordance with the [Commonwealth Grants Rules and Guidelines](#).

2.3 Legislative authority for this grant program

The Legislative Authority for grants under PTP is Section 32B of the *Financial Framework (Supplementary Powers) ACT 1997*, Schedule 1AB Item 103.

2.4 Portfolio Budget Statement

This program is made available under Outcome 4.3, Pharmaceutical Benefits, from the Department of Health Portfolio Budget Statements.

2.5 Grant opportunities available under PTP Tranche 1

The Government has agreed to fund trials in the following areas under PTP Tranche 1:

2.5.1 Pharmacy based screening and referral for diabetes

The objective of this trial is to assess the comparative effectiveness and cost-effectiveness of alternative pharmacy-delivered models of opportunistic assessment for diabetes in an asymptomatic, previously undiagnosed population.

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2.5.2 *Improved medication management for Aboriginal and Torres Strait Islander People through pharmacist advice and culturally appropriate services*

The objective of this trial is to address the high incidence of medication non-adherence amongst Aboriginal and Torres Strait Islanders by testing the provision of a flexible and culturally appropriate Medicine Safety and Adherence Flexible Education Service, delivered by community pharmacists.

2.5.3 *Improved continuity in the management of patients' medications when they are discharged from hospital*

The objective of this trial is to test the sharing of accurate and up-to-date data amongst community pharmacies, hospital staff and general practitioners as a means of reducing the number of hospital re-admissions caused by adverse medicines events that occur when patients are discharged from hospital.

All trials will need to:

- Focus on improved health outcomes for consumers;
- Take an integrated care approach in the context of other health system priorities and reforms; and
- Test innovative services in community pharmacy(ies).

3. Grant amounts

Approximately \$10 million has been allocated for PTP Tranche 1 over a three year period. The exact quantum of funding for each of the three grants will be determined by taking into account a number of factors, including the time, extent and nature of each trial.

Submitting a grant application does not guarantee that the applicant will receive a grant or the grant amount applied for.

4. When will funding be made available?

The first payment of funding to the successful applicant will occur in accordance with the grant agreement. See Section 10.1.

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5. Eligibility criteria

The Government identified, through research and development work, three topics to trial in pharmacies across Australia. This work occurred under previous Community Pharmacy Agreements. These topics will lead to improved health outcomes for consumers and address the Government's stated priorities with regard to continuity of care.

The Government wishes to commence trials in these areas as soon as possible. The Pharmacy Guild of Australia (the Guild) has demonstrated experience in delivering pharmacy programs and services, technical expertise and strong engagement across the pharmacy and other health sectors. Consequently, the Guild is best placed to undertake the proposed trials under PTP Tranche 1.

The only organisation eligible to apply for funding under PTP Tranche 1 is the Guild.

6. Eligible grant activities

6.1 What can the grant money be used for?

Funding of eligible trials may include the following components:

- Research functions, e.g. data collection and trial evaluation, including appropriate storage of data and transmission systems that ensure privacy and security for patient data;
- Patient management and collaboration with other health professionals;
- Payments to appropriately qualified pharmacists with the required level of competence to participate in the trial activities;
- Purchase of equipment and software to facilitate trial activities;
- Purchase of products such as testing equipment, point-of-care devices, and other consumables;
- Payments by the Guild to participating pharmacies and other organisations involved in the trial, which directly contribute to the outcomes of the trial;
- Payments by the Guild to project partners for undertaking activities related to the trial;
- Information materials related to the trials for pharmacists and patients; and
- Education and training packages for pharmacists and other trial participants.

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6.2 What can't the grant money be used for?

Grants **cannot** be used for the following activities:

- Activities with no demonstrable links to the objectives of PTP Tranche 1 as outlined in Section 2.2;
- Capital works, such as the purchase of any land, the purchase or construction of a completely new premises, the demolition (whether or not followed by the replacement) of the majority of an existing premises or works including minor capital works;
- Retrospective items/activities;
- Lobbying and activities undertaken by political organisations; and
- Activities that are funded through other departmental programs.

7. The selection process

For PTP Tranche 1, the department will use a targeted, non-competitive process to award grants under PTP Tranche 1. A targeted, non-competitive process is where the Guild is invited to submit an application for each proposed trial which will be assessed individually against the assessment criteria.

In this instance, as outlined in Section 5 above, the only eligible applicant will be the Guild.

The merits of an application relative to these guidelines and achieving value for money are the key considerations in assessing the application.

The department anticipates that assessment of applications will be finalised within 2-4 weeks of receipt of applications.

The funding period will commence two to four weeks after completion of assessment of applications and cease after three financial years. Funds must be expended by the end of the funding period on 30 June 2019.

7.1 How to apply for funding under a Grant Opportunity

The Approach to Market (ATM) Documentation will be supplied to the Guild and may consist of:

- These grant guidelines;
- An application form;
- The Department of Health's Standard Funding Agreement; and
- Any other relevant information.

8. Grant application process

8.1 Overview of application process

The Guild should read and understand these grant guidelines and all other information contained in the ATM documentation prior to submitting an application.

The Guild is responsible for ensuring that the application is complete and accurate. Giving false or misleading information may exclude the application from consideration.

The Guild must address all of the eligibility criteria and all assessment criteria to be considered for a grant. Please complete each section of the application form and ensure each requirement has been considered.

Please keep a copy of the application and any supporting papers.

The grant application will be acknowledged for receipt within two business days.

8.2 Timing for the application process

Applications must be submitted to the department by the closing date specified in the ATM documentation. The department will normally only accept a late application if it is the direct result of mishandling by the department. In all other circumstances, the department reserves the right not to accept late applications.

8.3 Table 1: Expected timing for this grant opportunity

Activity	Time
Application period	3-6 weeks
Assessment of applications	2-4 weeks
Approval of outcomes of selection process	2-4 weeks
Negotiations and Award of grant agreements	2-4weeks

8.4 Completing the application

The Guild must submit all grant applications on the relevant application form. Instructions are provided in the application form.

The Australian Government will not issue application forms or accept completed applications for this grant opportunity by fax or mail or in hardcopy.

The Guild is responsible for ensuring that the application is complete and accurate and submitted in accordance with the requirements of these Guidelines.

Amended or altered applications will not be accepted after the closing date and time.

The Guild should contact the department at Pharmacy.Trial.Programme@health.gov.au immediately if an error is discovered in an application after submission. The department may request clarification or additional information from the Guild that does not alter the substance of the application in response to an omission or error of form. The department is not bound to accept any additional information, or requests to change applications after the closing time.

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8.5 Questions during the application period

If the Guild has any questions during the application period, they should be directed to the department at Pharmacy.Trial.Programme@health.gov.au, the department will respond to emailed questions within three working days.

8.6 What are the assessment criteria?

The Guild is required to develop a research protocol which comprehensively describes the trial design and methodology and addresses the following criteria:

Criterion 1: Demonstrated sound knowledge of the pharmacy sector and the organisational capacity to undertake the trial to a high standard.

Criterion 2: Evidence that supports patient need for the proposed service.

Criterion 3: Scientific rigour of the research protocol.

9. Assessment of grant applications

9.1 Who will assess applications?

The submitted application for each trial will be assessed against the selection criteria for the available funding.

The Trials Advisory Group (TAG) has been established by the department as an expert advisory body for the Pharmacy Trials Program. The TAG's advice will inform the Assessment Committee's consideration of applications, the department may also consider information that is available through the normal course of business.

The department will then consolidate this information to make recommendations to the approver.

The Guild will be given the option to discuss points of clarity concerning their application(s) during this process.

The Guild will be advised of the outcomes of the application in writing, following a decision by the Approver. Advice to the successful applicant will contain details of any specific conditions attached to the grant.

9.2 How will applications for funding be assessed?

Applications will be assessed through a two stage process.

Stage 1 Eligibility Requirements

Noting that this is a targeted, non-competitive approach to the Guild, the applications must also satisfy all Eligibility Criteria in order to be considered for funding. Eligibility Criteria are as follows:

1. The application is completed in English.
2. The Declaration is signed (Section 5) and Acknowledgement (Section 4) is completed.

Stage 2 –Selection Criteria

Further assessment will be made against the Assessment Criteria set out at Section 8.6.

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Informed by the TAG's advice, the department will undertake assessment of applications and will consider the Guild's response to each Assessment Criterion using the following rating scale:

Rating (for individual criterion)	Rank
High quality – response to this criterion addresses all or most sub-criteria to a higher than average standard. Additional evidence* is available and confirms good performance against this criterion.	Highly Suitable
Good quality – response against this criterion meets most sub-criteria to an average and acceptable level. Some additional evidence* is available and provides some support for claims against this criterion.	Suitable
Poor quality – poor claims against this criterion, meets some or none of the sub-criteria. Additional evidence* is unavailable, not relevant or lacking in detail.	Not Suitable

Additional evidence may include specified attachments to the application, previous departmental experience with the Guild or information from other areas of the assessment of the criterion.

The applications must receive an **overall** score of Suitable or above to be recommended for funding.

Value with Relevant Money

All applications will be assessed to ensure that they deliver value with relevant money. They will be assessed against the aims, objectives and priorities of PTP Tranche 1 to determine eligibility for funding including capacity to meet program outcomes and to provide value with relevant money.

The principles of value with relevant money include:

- the risks, meeting the objectives of the program and government policy, innovation and potential performance;
- the most effective targeting of funds to meet program/policy outcomes as outlined in these Grant Guidelines; and
- As an appropriate funding amount/budget request commensurate with the scale of the project or activities being undertaken.

9.3 Feedback on applications

If the Guild is unsuccessful, they may request feedback on the application from the department within a period of six weeks of being advised of the outcome. The department will provide feedback within six weeks of receiving a request for feedback.

9.4 Who will approve grants?

Following assessment, the Assessment Committee will make recommendations to the Funding Approver on the merits of the applications. Funding approval is at the discretion of the Approver, who will consider whether the recommendations make efficient, effective, and ethical use of Commonwealth resources, as required by Commonwealth legislation, and whether any specific requirements should be imposed as a condition of funding.

The Approver for funding under PTP Tranche 1 is the Minister for Health or the departmental delegate nominated for the purposes of PTP Tranche 1. The departmental delegate is the First Assistant Secretary, Pharmaceutical Benefits Division.

10. Successful grant applications

10.1 Grant agreement

If the application is successful, the Guild will be required to enter into a legally binding grant agreement with the Commonwealth represented by the Department of Health. The department may use the [Department of Health's Standard Funding Agreement](#). The standard terms and conditions for the grant agreement will apply and cannot be changed. Any additional conditions attached to the grant will be identified in the grant offer or during the grant agreement negotiations.

The Guild will be required to meet certain milestones and deliverables under each activity that will be set out in the funding agreement.

The department will negotiate with the Guild, if successful, with the aim of having grant agreements signed and returned to the department to enable timely commencement of activities under the Grant Opportunity. If there are unreasonable delays in negotiating a grant agreement, the grant offer may be withdrawn.

The department is committed to a comprehensive and systematic approach to the effective management of potential opportunities and adverse effects. Any contractual arrangement may be managed according to its level of risk to the Commonwealth. As such, PTP Tranche 1 may be subject to a risk management assessment prior to the negotiation of any contractual arrangement and periodically thereafter.

Where the Guild fails to meet the obligations of the grant agreement, the department may cease grant funding after attempting to rectify the issue with the grant recipient. Further details will be provided in the Guild's funding agreement with the department.

Financial commitments in expectation of receiving the grant should not be entered into until a grant agreement has been signed by the Commonwealth.

11. Grant announcements

If successful, the grant will be listed on the department's website 14 days after the date of effect as required by the Commonwealth Grants Rules and Guidelines.

12. Delivery of grant activities

12.1 Applicant's responsibilities

If successful, the Guild must carry out the grant activities in accordance with these guidelines and the grant agreement, which includes the standard terms and conditions, any supplementary conditions and the schedule. The schedule to the funding agreement will outline the specific grant requirements.

The Guild will be responsible for:

- Ensuring that the terms and conditions of the grant agreement are met and that the activity is managed in an efficient and effective manner;
- Ensuring the effective and efficient use of grant funds;
- Employing and managing staff required to deliver the activity;

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- Maintaining contact with the department and advising of any emerging issues that may impact on the success of the activity;
- Identifying, documenting and managing risks and putting in place appropriate mitigation strategies;
- Meeting milestones and other timeframes specified in the grant agreement;
- Complying with record keeping, reporting and acquittal requirements in accordance with the grant agreement;
- Participating in activity evaluation as required for the period specified in the grant agreement; and
- Ensuring that activity outputs and outcomes are in accordance with the grant agreement.

12.2 Successful applicant's reporting requirements

The timing of progress reports will be negotiated and form part of the final funding agreement.

Reports may include:

- quarterly or six-monthly progress reports;
- annual progress reports;
- end of agreement and financial acquittal reports; and
- Activity evaluation report.

The progress reports will address the requirements set out in the work plan and project budget, and will be assessed accordingly by the department.

Progress reports should assess overall Activity effectiveness and measure the performance of each Activity against the agreed performance indicators.

Progress reports should also include the following:

- any potential project issues that could impact on timelines and quality of deliverables;
- approaches or strategies for resolving any identified issues;
- variance between proposed budget and actual expenditure (subject to approval specified in the funding agreement);
- acquittals of funding and expenditure; and
- Recommendations for improving the performance of the Activity against the performance indicators.

The Guild, if successful, will also be required to provide ad hoc advice to the department when requested in relation to the funded Activity.

The Guild, if successful, will be required to take out and maintain, for the period specified in the funding agreement, all types and amounts of insurance necessary to cover the obligations of the organisation in relation to the activity.

12.3 The Department of Health's responsibilities

The department will:

- meet the terms and conditions of the grant agreement established with each grant recipient;
- administer the operation of the grant in a timely manner;
- use the Australian Government's default invoice process – Recipient Created Tax Invoices; and
- Evaluate the grant recipient's performance against the grant outcomes.

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12.4 Grant payments and taxation implications

Payments will be made in accordance with the grant agreement. Before any payments are made, the Guild will be required to provide:

- Evidence of meeting the associated milestone in the grant agreement; and
- Any other conditions of payment (e.g. evidence of purchase of equipment, satisfactory progress report, approvals, other documentation etc).

If the application is successful, the Guild should consider seeking guidance from a tax advisor or the [Australian Taxation Office](#) about the implications of receiving a grant, prior to entering into a grant agreement.

12.5 Evaluation

The department will conduct an evaluation of each Grant Opportunity under the Pharmacy Trial Program to determine whether the outcomes and objectives have been achieved. The grant agreement requires the Guild to provide information to assist in this evaluation.

12.6 Acknowledgement

All publications related to grants under PTP Tranche 1 should acknowledge the Commonwealth as follows:

“This activity received grant funding from the Australian Government”.

13. Probity

The Australian Government is committed to ensuring that the grants process is fair, in accordance with the published guidelines, incorporates appropriate safeguards against fraud, unlawful activities and other inappropriate conduct, and is consistent with the Commonwealth Grants Rules and Guidelines.

Note: These guidelines may be varied from time-to-time by the Department of Health as needed. Amended guidelines will be published on the department’s website.

13.1 Complaints process

The Department of Health’s complaints procedures apply to complaints that arise in relation to grant programs. All complaints relating to a grant process must be lodged in writing. More information can be found on the [Grants and Procurement Complaints Procedures](#) page on the department’s webpage.

Any enquiries relating to grant decisions for this Program should be directed to Pharmacy.Trial.Programme@health.gov.au

If the Guild is dissatisfied with the way in which the Department of Health has handled a complaint, the Guild may wish to complain to the Commonwealth Ombudsman. The Ombudsman will usually decline to investigate a complaint unless the matter has first been raised directly with the department.

[The Commonwealth Ombudsman](#) can be contacted on: Phone (Toll free): 1300 362 072

Email: ombudsman@ombudsman.gov.au

13.2 Conflict of interest

A conflict of interest, or perceived conflict of interest, may exist if the department's staff, any member of an advisory panel or expert committee, and/or the Guild or any of the Guild's personnel:

- Has a relationship (whether professional, commercial or personal) with a party who is able to influence the application assessment process, such as an Australian Government officer;
- Has a relationship with, or interest in, an organisation, which is likely to interfere with or restrict the Guild from carrying out the proposed activities fairly and independently; or
- Has a relationship with, or interest in, an organisation from which they will receive personal gain as a result of the organisation receiving funding under this Program.

The Guild will be required to declare, as part of the application, any perceived or existing conflicts of interests or that, to the best of their knowledge, there is no conflict of interest.

Where the Guild subsequently identifies that an actual, apparent, or potential conflict of interest exists or might arise in relation to a grant application, the Guild must inform the department in writing immediately. The chair of the Assessment Committee will be made aware of any conflicts of interest and will address them in compliance with Australian Government policies and procedures.

Conflicts of interest for Australian Government staff will be handled in compliance with the [Australian Public Service Commission policies and procedures](#).

13.3 Privacy: confidentiality and protection of personal information

Any personal information the Guild provides is protected under the *Privacy Act 1988*. It can only be disclosed to someone else if the Guild is given reasonable notice of the disclosure; where disclosure is authorised or required by law or is reasonably necessary for the enforcement of the criminal law; if it will prevent or lessen a serious and imminent threat to a person's life or health; or if the Guild has consented to the disclosure.

The Australian Government may also use and disclose information relating to the Guild and recipients under this Program in any other Australian Government business or function, including providing information to the Australian Taxation Office for compliance purposes.

13.4 Freedom of information

All documents in the possession of the Australian Government, including those in relation to PTP Tranche 1, are subject to the *Freedom of Information Act 1982* (FOI Act).

The purpose of the FOI Act is to give members of the public rights of access to information held by the Australian Government and its entities. Under the FOI Act, members of the public can seek access to documents held by the Australian Government. This right of access is limited only by the exceptions and exemptions necessary to protect essential public interests and private and business affairs of persons in respect of whom the information relates.

All Freedom of Information requests must be referred to the Freedom of Information Coordinator in writing.

By mail: Freedom of Information Coordinator
 FOI Unit
 Department of Health
 GPO Box 9848
 Canberra ACT 2601

By email: foi@health.gov.au

14. Consultation

The department has undertaken extensive consultation on PTP.

This commenced with a consultation on 26 October 2015 with pharmacy, medical and consumer peak bodies and organisations, where stakeholders were invited to provide input on essential principles and priority areas for funding of trial programs. Over twenty bilateral meetings have been held with stakeholders, and in March 2016, a discussion paper was released which provided comprehensive information about PTP.

These guidelines reflect stakeholders' views about how PTP objectives could be achieved, and the principles and criteria which could be applied.