



Australian Government
Department of Health

**Invitation to Apply
to supply
PBS Medicines and NDSS Products**

in accordance with the Community Service Obligation (CSO) Funding Pool and
National Diabetes Services Scheme (NDSS)

**Issued by the Commonwealth of Australia as represented by the
Department of Health**

Reference: CSO Application E16-4341

Enquiry Cut-off Date: 2pm, 27 October 2016 (local time in Canberra, ACT)

Application Closing Time: 2pm, 3 November 2016 (local time in Canberra, ACT)

Contact Officer: Carol Sinclair

Contact Address: cso.application@health.gov.au

PLEASE NOTE:

Applicants should plan to lodge their Application well before the Closing Time to minimise the possibility of any unforeseen circumstances arising that may cause the Applicant to miss the Closing Time.

CONTENTS

PART 1 - OVERVIEW AND APPLICATION LODGEMENT	4
1. THE DEPARTMENT	4
2. OVERVIEW OF SERVICES	4
3. INDICATIVE TIMETABLE	5
4. REGISTRATION	5
5. COMMUNICATION	5
6. ELECTRONIC LODGEMENT	6
7. APPLICATION CLOSING TIME AND DATE	6
8. PREPARING TO LODGE AN APPLICATION	6
PART 2 – APPLICATION REQUIREMENTS	7
9. ELIGIBILITY REQUIREMENTS	7
10. FORMAT REQUIREMENTS	7
11. FORMAT OF APPLICATIONS	7
12. CONSENTS FOR SECURITY, PROBITY AND FINANCIAL CHECKS	8
PART 3 - ASSESSMENT PROCESS	9
13. ASSESSMENT CRITERIA	9
14. EXCLUSION OF APPLICATIONS	10
15. ASSESSMENT APPROACH	10
16. CLARIFICATION	11
17. NEGOTIATIONS	11
18. COMPLAINTS PROCEDURE	11
PART 4 - OTHER TERMS AND CONDITIONS	12
19. MATERIAL CHANGE TO APPLICANT	12
20. CONFLICT OF INTEREST	12
21. APPLICANT CONDUCT	12
22. COST OF PREPARING AND SUBMITTING APPLICATION	13
23. APPLICANTS DUE DILLIGENCE	13
24. NO CONTRACT OR UNDERTAKING	13
25. ACCEPTANCE	14
26. THE DEPARTMENT'S RIGHTS	14

27. PUBLICITY	15
28. OWNERSHIP AND USE OF APPLICATION DOCUMENTS	15
29. INTELLECTUAL PROPERTY RIGHTS	15
30. CONFIDENTIALITY	16
PART 5 - APPLICABLE LAWS AND POLICIES	17
31. APPLICABLE LAW	17
32. AUDIT AND ACCESS	17
33. FOI AND OTHER RIGHTS TO ACCESS INFORMATION	17
34. PRIVACY	17
35. WORKPLACE GENDER EQUALITY	18
36. WORK HEALTH AND SAFETY	18
37. ANTI-TERRORISM	18
38. ANTI-MONEY LAUNDERING	18
39. ILLEGAL WORKERS	18
40. INDIGENOUS PROCUREMENT POLICY	19
PART 6 - STATEMENT OF REQUIREMENT	20
1. BACKGROUND	20
2. PARTICIPATION	20
3. COMPLIANCE WITH CSO OPERATIONAL GUIDELINES	21
4. TERM OF THE DEED	22
5. OPERATIONAL ENVIRONMENT	22
6. GENERAL OBLIGATIONS OF THE DISTRIBUTOR	23
7. REPORTING REQUIREMENTS	24
8. EVALUATION AND MONITORING REQUIREMENTS	24
9. PAYMENT ARRANGEMENTS	24
10. INSURANCE REQUIREMENTS	25
PART 7 - GLOSSARY	26
SCHEDULE 1 - APPLICANT'S RESPONSE SCHEDULE	30
SCHEDULE 2 - DEED OF AGREEMENT	31
SCHEDULE 3 - CSO OPERATIONAL GUIDELINES	32

PART 1 - OVERVIEW AND APPLICATION LODGEMENT

1. THE DEPARTMENT

- 1.1 The Department of Health's (Department) vision is to achieve better health and wellbeing for all Australians. The Department aims to achieve its vision through strengthening evidence-based policy advice, improving program management, research, regulation and partnerships with other government agencies, consumers and stakeholders.
- 1.2 The Pharmaceutical Benefits Scheme (**PBS**) provides Australians with access to a wide range of medicines, allows for choice between different medicines for patients and doctors, and is affordable for individuals and the Australian community.
- 1.3 The National Diabetes Services Scheme (**NDSS**) enhances the capacity of over one million Australians with type 1, type 2, gestational and other diabetes to understand and manage their life with diabetes. The NDSS aims to ensure people have timely, reliable and affordable access to the supplies and services they require to effectively self-manage their diabetes.

2. OVERVIEW OF SERVICES

- 2.1 The Commonwealth of Australia represented by the Department is seeking responses to this Invitation to Apply (ITA).
- 2.2 The Department is seeking Applications from eligible entities (**Distributors**) to supply:
- a) PBS Medicines and b) NDSS Products (collectively **CSO Products**) through Community Pharmacies and other designated Access Points (**Distribution Points**).
- 2.3 To be considered eligible entities, Applicants must be fully compliant with the CSO Operational Guidelines provided at Schedule 3 of this ITA.
- 2.4 The detailed specifications and requirements for the Services are set out in the Statement of Requirement, Part 6 to this ITA. The Department proposes to appoint the successful Applicant/s in accordance with the Draft Deed set out in Schedule 2 to this ITA.
- 2.5 Applicants should note that it is the Department's intention to enter into the same Deed of Agreement with each appointed Distributor. Negotiation of individual or alternate clauses for each separate Distributor will not be permissible.
- 2.6 Applicant's attention is also drawn to the assessment criteria outlined in more detail in the Applicants Response Schedule at Schedule 1 to this ITA and categorised into:
- a) Eligibility Requirements;
- b) Information and Compliance Requirements; and
- c) Service Requirements.

3. INDICATIVE TIMETABLE

3.1 The following is an indicative timetable for this process:

Activity	Timing
Issue of ITA	29 September 2016
Enquiry Cut-Off Date	2pm, 27 October 2016
Lodgement Closing Time	2pm, 3 November 2016
Execution of Deed of Agreement with appointed organisations	December 2016
Commencement of Services	1 January 2017

4. REGISTRATION

4.1 **Potential Applicants must register interest in responding to this ITA.** This will ensure all potential applicants receive any updates/changes or clarifications to the ITA issued by the Department.

4.2 The Department will also use this information to provide responses to questions received by potential Applicants.

4.3 Potential Applicants that do not register risk not receiving accurate information which may exclude them from meeting the compliance criteria.

4.4 Register by email to:

Email: cso.application@health.gov.au

4.5 The email must provide the following details:

- a. Organisation Name;
- b. Contact Name;
- c. Contact Email Address;
- d. Additional Contact Name; and
- e. Additional Contact Email Address.

5. COMMUNICATION

5.1 Enquiries about this ITA must be made by email addressed to:

Email: cso.application@health.gov.au

5.2 The Department will provide answers to any reasonable enquiry from a potential Applicant that is received before the Enquiry Cut-Off Date set out in clause 3, in which case:

- a. questions and related answers will generally be disclosed to all potential Applicants via their registered email address (without disclosing the source of the questions); and
 - b. any Applicant Confidential Information contained in a question (that is expressly nominated as such by the potential Applicant and agreed to by the Department) will be removed prior to responses being provided.
- 5.3 All communications related to this ITA should be addressed to the Contact Officer (clause 5.1 above) and not to other Departmental officers or other persons. An Applicant who communicates other than to the Contact Officer runs the risk of not receiving accurate information which may exclude them from meeting the compliance criteria.

6. ELECTRONIC LODGEMENT

- 6.1 Applications must be lodged electronically to cso.application@health.gov.au before the Closing Time and in accordance with the lodgement procedures set out in this ITA.
- 6.2 If Applicants need to lodge material that cannot be submitted via email they should contact the Contact Officer prior to Closing Time to make arrangements for its submission.

7. APPLICATION CLOSING TIME AND DATE

- 7.1 Applications must be lodged before 2:00pm local time, ACT (AEDT) on 3 November 2016 (the **Closing Time**).
- 7.2 For the purposes of determining whether an Application has been lodged before the Closing Time, the imprinted time on the email submission will be conclusive.

8. PREPARING TO LODGE AN APPLICATION

Application File Formats, Naming Conventions and Sizes

- 8.1 The format of the Application must be Microsoft Word 2003 (or above). If providing spreadsheet data the format can be Microsoft Excel 2003 (or above).
- 8.2 The Application file name/s should:
- a. incorporate the Applicant's company name; and
 - b. reflect the various parts of the Application they represent, where the Application comprises multiple files.
- 8.3 Applications must be completely self-contained. No hyperlinked or other material may be incorporated by reference.

PART 2 – APPLICATION REQUIREMENTS

9. ELIGIBILITY REQUIREMENTS

- 9.1 If the Department considers that an Applicant does not satisfy the following eligibility requirements, that Application may be excluded from further consideration.

Item	Eligibility Requirements
1	Applicants must not have had any judicial decisions against it (excluding decisions under appeal) relating to employee entitlements and have not paid the claim.
2	Applicants must comply with all Commonwealth policy.
3	Applicants must have the legal, technical and financial abilities to fulfil the requirements of the services.
4	Applicants must be compliant with the CSO Operational Guidelines provided at Schedule 3 of this ITA.

10. FORMAT REQUIREMENTS

- 10.1 If the Department considers that an Application does not satisfy all of the following Format Requirements, that Application may be excluded from further consideration.

Item	Format Requirements
1	The Application (including attachments and supporting material) must be in English and measurements must be expressed in Australian legal units of measurement.
2	The Application must include a signed Declaration as provided at Attachment E of the Applicant's Response Schedule.

- 10.2 Without limiting the Department's other rights in this Application the Department may, in its sole and absolute discretion, allow the Applicant to correct any error of form in an Application that appears to be unintentional, by lodging a correction or additional information, in writing in accordance with the direction of the Department.

11. FORMAT OF APPLICATIONS

- 11.1 Applications should be completed in accordance with the Applicant's Response Schedule provided, noting the following:
- a. all relevant information should be provided in response to the information requirements;
 - b. where a response to a particular requirement is covered in another section of the Application, a cross reference to that section should be provided or the Applicant should repeat the information; and
 - c. Applicants may include additional or support materials (as supplements or attachments) noting that Applicants are discouraged from including generic marketing information that does not address the Assessment Criteria.

- 11.2 Applicants who wish to:
- a. negotiate any of the provisions of the Draft Deed; or
 - b. claim confidentiality in relation to any aspects of their Application;
- should complete Statement D in the Applicants Response Schedule.

12. CONSENTS FOR SECURITY, PROBITY AND FINANCIAL CHECKS

- 12.1 The Department may perform such security, probity and financial checks and procedures as the Department, at its absolute discretion, may determine are necessary in relation to:
- a. the Applicant, its officers, employees, partners, associates and subcontractors;
 - b. Related Bodies Corporate of the Applicant and its subcontractors and their officers, employees and subcontractors; and
 - c. consortium members.
- 12.2 An Application may be rejected by the Department if the Applicant does not provide, at its own cost, all reasonable assistance to the Department in this regard.

PART 3 - ASSESSMENT PROCESS

13. ASSESSMENT CRITERIA

13.1 The Department will use the following categories of Assessment Criteria in the assessment of Applications:

- (i) **Eligibility Requirements** (which includes legislative and format requirements);
- (ii) **Information and Compliance Requirements** (corporate information and policy compliance); and
- (iii) **Service Requirements** (information about Applicant's capacity, and capability in relation to the Services required, including an assessment of any risks in the Applicant's service delivery solution and management).

Summary of Service Requirements (see Schedule 1: Applicant Response Schedule)
Licences
Past Performance
Capability – Service Delivery and Management
Single Point of Contact
Quality of CSO Products
Supply to any Community Pharmacy and/or Access Point
Supply any CSO Products
Stocking Requirements
Timely Supply
Pricing: PBS Medicines
Pricing: NDSS Products
Daily Delivery
Rural and Remote
Low Volume PBS Medicines
Electronic Data Management
Reporting and Evaluation
Business Continuity Plan
Risk Management

13.2 The Department may:

- a. consider any part of an Application in the Assessment of any or all of the Assessment Criteria; and
- b. make independent inquiries in relation to an Applicant.

14. EXCLUSION OF APPLICATIONS

- 14.1 Without limiting any other provision of this ITA that gives the Department the right to exclude Applications on other grounds, the Department reserves the right to reject an Application, at its absolute discretion, if:
- a. the Application is incomplete;
 - b. the Applicant or Application does not comply with this ITA;
 - c. the Applicant is not fully capable of undertaking a contract in the form of the Draft Deed;
 - d. the Application is rated unsuitable or unsatisfactory against one or more of the Assessment Criteria;
 - e. the Application contains statements that qualify or are contrary to the Applicant Declaration to this ITA;
 - f. in the Department's opinion the Application contains a false declaration;
 - g. the Application contains false or misleading information or statements;
 - h. the Applicant, or a director or officer of the Applicant, is insolvent or bankrupt;
 - i. the Applicant has an actual, potential or perceived conflict of interest that cannot be managed to the satisfaction of the Department acting in its absolute discretion; or
 - j. there has been a significant deficiency in the performance of a substantive requirement or obligation under a prior agreement.

15. ASSESSMENT APPROACH

- 15.1 Applications will be assessed to determine how well they meet each Assessment Criterion.
- 15.2 The Department may also include an assessment of risk to the Department in general and to this process, in particular in its Assessment against each Assessment Criterion. The Applicant's Compliance Statements will be taken into account in the assessment of risk.
- 15.3 As part of its Assessment of Applications, the Department may, in its sole and absolute discretion:
- a. ask Applicants to undertake presentations;
 - b. ask Applicants to provide written clarification of various aspects of their Applications;
 - c. ask Applicants to provide further information to confirm their financial viability and commercial stability;
 - d. have discussions or interviews with Applicants in order to seek further clarification of their Applications;
 - e. visit Applicants' sites; and
 - f. have discussions with or undertake visits to customers of Applicants and their Subcontractors, whether or not those customers are listed as referees in the Applicants' Applications.

- 15.4 The Department may choose to undertake the activities set out in this clause in relation to some Applicants only. Presentations, interviews and site visits may be subject to additional terms and conditions that are advised by the Department to Applicants who have been invited to participate in each activity.
- 15.5 Any costs incurred by the Applicant in complying with this clause will be borne by the Applicant.

16. CLARIFICATION

- 16.1 Where the meaning of an Application is unclear or there is an apparent error of form, the Department may seek clarification from the Applicant.
- 16.2 Failure to supply clarification to the satisfaction of the Department may cause the Application to be excluded from consideration.

17. NEGOTIATIONS

- 17.1 Negotiations may be undertaken with Applicants in the sole and absolute discretion of the Department.
- 17.2 During the negotiation phase of this process, the Department may engage in detailed discussions and negotiations, including parallel negotiations, with the goal of maximising the benefits of the project, as measured using the Assessment Criteria. As part of this process, those Applicants participating in the negotiation phase may be asked to improve any or all aspects of their Application. The Department's intention is that it will select Applicant(s) after all material issues have been resolved.
- 17.3 Without limiting its other rights under this ITA, in the event that the Department concludes that during negotiations an Applicant has retracted, or attempts to retract, any part of its Application, the Department, in its sole and absolute discretion, reserves the right to:
- a. disqualify that Applicant's Application;
 - b. terminate the process;
 - c. re-enter negotiations or parallel negotiations with other Applicants; or
 - d. exercise any other right reserved to the Department under law or elsewhere in this ITA.

18. COMPLAINTS PROCEDURE

- 18.1 Any complaints about this process should be made in writing and sent to the Contact Officer's email address.

PART 4 - OTHER TERMS AND CONDITIONS

19. MATERIAL CHANGE TO APPLICANT

- 19.1 An Applicant must notify the Department if, following lodgement of its Application, there occurs:
- a. an event that has the effect of materially altering either the composition or control of the Applicant or the business of the Applicant; or
 - b. any material change to the compliance status of the Applicant; or
 - c. any material change to the proposed basis on which the Applicant will deliver the Services, or have access to the necessary and appropriate skills, resources, nominated key personnel, nominated Subcontractors or corporate or financial backing to provide the Services, on the terms of the Draft Deed.
- 19.2 If the Department receives notice, or becomes aware of an event under clause 19.1a, the Department may allow (on terms it considers appropriate) the substitution of the Applicant with another legal entity upon receipt of a joint written request from or on behalf of the Applicant and the other legal entity. If the Department allows the substitution, it will evaluate the Application in its original form prior to the event, except that the impact of the event on the information provided in the Application may be taken into account.
- 19.3 If the Department receives notice, or becomes aware of an event under clause 19.1b or 19.1c, or the Commonwealth does not allow substitution, or substitution is not requested, under clause 19.1a, the Department may either exclude the Application from consideration or consider the Application taking into account the impact of the changed circumstances on the information provided in the Application.

20. CONFLICT OF INTEREST

- 20.1 If at any time prior to entering into a contract for the Services, an actual or potential conflict of interest arises or may arise for any Applicant, other than that already disclosed, that Applicant should immediately notify the Department in writing.
- 20.2 If any actual or potential conflict is notified, or the Department becomes aware of any actual or potential conflict, the Department may, in its absolute discretion:
- a. disregard the Application submitted by such an Applicant;
 - b. enter into discussions to seek to resolve such conflict of interest; or
 - c. take any other action it considers appropriate.

21. APPLICANT CONDUCT

- 21.1 Applicants must not, and must ensure that their officers, employees, agents and advisors do not, in relation to the preparation, lodgement or assessment of Applications:
- a. make any false or misleading or deceptive claim or statement;
 - b. improperly obtain Confidential Information;

- c. receive improper assistance from any existing or former officer or employee of the Department;
 - d. engage in anti-competitive conduct, unlawful, unethical or other similar conduct with any other Applicant or other person;
 - e. attempt to improperly influence an officer or employee of the Department or violate any applicable laws regarding the offering of inducements; or
 - f. approach any officer or employee of the Department other than in the manner set out in this ITA.
- 21.2 The Department may exclude an Application from consideration if the Applicant fails to comply with the requirements set out in this clause.

22. COST OF PREPARING AND SUBMITTING APPLICATION

- 22.1 In no circumstances will the Department be responsible for any costs incurred by an Applicant in preparing an Application, or associated expenses related to this ITA.

23. APPLICANT'S DUE DILLIGENCE

- 23.1 Applicants are deemed to have:
- a. examined this ITA, and any other documents referenced or referred to in this ITA, and any other information made available in writing by the Department to Applicants for the purposes of submitting an Application;
 - b. examined all other information which is obtainable by the making of reasonable and timely inquiries and relevant to the risks, contingencies and other circumstances having an effect on their Application; and
 - c. satisfied themselves as to the correctness and sufficiency of their Application, for the due and proper performance and delivery of the Services.
- 23.2 It is the responsibility of Applicants to obtain all information necessary or convenient for the preparation of their Application.
- 23.3 Applicants must not rely, and are deemed not to have relied, upon any statement or representation by the Department, whether before or after the date of this ITA, in connection with this process, unless that statement or representation is made in writing by the Contact Officer for this ITA.
- 23.4 Applicants should obtain their own legal and other professional advice about this ITA and its requirements including obligations in respect of the Draft Deed.

24. NO CONTRACT OR UNDERTAKING

- 24.1 Nothing in this Application or in any Application or by the submission of an Application (in part or together) creates, or is to be construed to create, any binding contract or other legal relationship (express or implied) between the Commonwealth and any Applicant.

25. ACCEPTANCE

- 25.1 Acceptance of the appointed Distributors will be subject to the execution of a Deed between the Commonwealth and the Applicant substantially in the form of the Draft Deed at Schedule 2.

26. THE DEPARTMENT'S RIGHTS

- 26.1 The Department reserves the right to:
- a. vary the timing and processes;
 - b. change or suspend the process;
 - c. terminate the process;
 - d. remove any Application from consideration where in the opinion of the Department:
 - (i) it is in the public interest to do so;
 - (ii) the Applicant does not meet a requirement;
 - (iii) the Applicant is not fully capable of undertaking the Deed; or
 - (iv) this ITA otherwise allows for the exclusion of the Applicant.
 - e. enter into a contract or other binding relationship outside the ITA process with a person on such terms as the Department in its absolute discretion accepts without prior notice to any Applicant where in the opinion of the Department:
 - (i) it is in the public interest to do so;
 - (ii) no Applicant meets a requirement; or
 - (iii) no Applicant is fully capable of undertaking the Deed.
 - f. enter into a contract on terms different to that specified in this ITA;
 - g. add an Applicant or select and negotiate with a third party who has not submitted an Application on such terms as the Department in its absolute discretion accepts without prior notice to any Applicant where in the opinion of the Department:
 - (i) it is in the public interest to do so;
 - (ii) no Applicant meets a requirement; or
 - (iii) no Applicant is fully capable of undertaking the Deed.
 - h. call for new Applications;
 - i. publish or disclose the names of Applicants (whether successful or unsuccessful);
 - j. allow or not allow a related body corporate within the meaning of the *Corporations Act 2001* (Cth) to take over an Application in substitution for the original Applicant;
 - k. enter into negotiations with any Applicant; or

1. cancel, add to or amend the information, requirement, terms, procedures or processes set out in this ITA.
- 26.2 If the Department does vary this ITA or process, the Department will endeavour to inform any potential Applicants who have registered interest in responding to this ITA as per clause 4 of this ITA.
- 26.3 The Department will not be liable or in any way responsible for any failure to inform a potential Applicant of a change relating to this ITA or any other matter arising by the Department exercising any of its rights.

27. PUBLICITY

- 27.1 The Applicant may not issue any information, publication, document or article for publication in any media which includes details of the Services under the Contract or which otherwise refers or is connected to the Department or this ITA process, without the prior written approval of the Department.

28. OWNERSHIP AND USE OF APPLICATION DOCUMENTS

- 28.1 Without affecting any intellectual property that may exist in an Application, all Application documents (including paper and electronic copies) become the property of the Department on submission.
- 28.2 Without prejudice to any other right of the Department under this ITA or at law, the Department may copy, amend, disclose or allow the disclosure of, or otherwise deal with, an Application or any information contained in or relating to any Application (at any time) for any of the following purposes:
 - a. evaluating and clarifying Applications;
 - b. negotiation of the Deed with the Applicant or any other Applicant;
 - c. managing any resultant agreement with the Applicant or any other Applicant;
 - d. audit, governmental and Parliamentary reporting requirements; and
 - e. responding to any disputes about this process or requests from Parliament or a Parliamentary Committee.
- 28.3 The Department may make copies of the Application as necessary for its purposes.

29. INTELLECTUAL PROPERTY RIGHTS

- 29.1 All intellectual property that exists in the information contained in this ITA, or any related or attached material, remains the property of the Department.
- 29.2 Each Applicant is permitted to use this ITA for the purpose only of compiling its Application and, in the case of the Applicant(s) selected through this process, for negotiating the Deed with the Department.
- 29.3 Such intellectual property rights as may exist in an Application will remain the property of the Applicant.

30. CONFIDENTIALITY

- 30.1 The Department will, subject to this Application, endeavour to treat the following information as confidential:
- a. all Applications received prior to the award of a contract;
 - b. all unsuccessful Applications, following the award of a contract;
 - c. all successful Applications following the award of a contract but only to the extent that the:
 - (i) appointed Applicant requests that specific information in that Application be kept confidential; and
 - (ii) Department has determined that specific information is to be kept confidential in accordance with the [Guidance on Confidentiality](#) from the Department of Finance and has agreed, pursuant to the Deed with the appointed Applicant, to keep that information confidential.
- 30.2 The Department will not be taken to have breached any obligation to keep information provided by Applicants confidential to the extent that the information is:
- a. disclosed by the Department to its advisers, officers, employees or subcontractors solely in order to conduct this process or to prepare and manage any resultant contract;
 - b. disclosed to the Department's internal management personnel, solely to enable effective management or auditing of this process;
 - c. disclosed by the Department to the responsible Minister;
 - d. disclosed by the Department in response to a request by a House or a Committee of the Parliament of the Commonwealth of Australia;
 - e. shared by the Department within the Department's organisation, or with another Commonwealth entity, where this serves the Commonwealth's legitimate interests;
 - f. authorised or required by law to be disclosed;
 - g. disclosed to meet the Department's reporting or accountability requirements, including, without limitation:
 - (i) under the *Public Governance, Performance and Accountability Act* (Cth) or other legislation;
 - (ii) to the Australian National Audit Office or any other auditor appointed by the Department;
 - (iii) to the Commonwealth Ombudsman; or
 - h. in the public domain otherwise than due to a breach of the relevant obligations of confidentiality.

PART 5 - APPLICABLE LAWS AND POLICIES

31. APPLICABLE LAW

- 31.1 The law applying in the Australian Capital Territory applies to this ITA and this ITA process. Each Applicant must comply with all relevant laws in preparing and lodging its Application and taking part in this process.

32. AUDIT AND ACCESS

- 32.1 The attention of Applicants is drawn to the *Auditor-General Act 1997* (Cth), which provides the Auditor-General or an authorised person with a right to have, at all reasonable times, access to information, documents and records.
- 32.2 In addition to the Auditor-General's powers under the *Auditor-General Act 1997* (Cth), if an Applicant is chosen to enter into a Deed, the Applicant will be required to provide the Auditor-General or an authorised person with access to information, documents, records and Department assets, including those on the Applicant's premises. This will be required at reasonable times on giving reasonable notice for the purpose of carrying out the Auditor-General's functions and will be restricted to information and assets which are in the custody or control of the Applicant, its employees, agents or Subcontractors, and which are related to the Deed. Such access will apply for the term of the Deed and for a period of 7 years from the date of expiration or termination of the Deed.
- 32.3 Applicants should obtain, and will be deemed to have obtained, their own advice on the impact of the *Auditor-General Act 1997* (Cth) on their participation in the Application.

33. FOI AND OTHER RIGHTS TO ACCESS INFORMATION

- 33.1 The attention of Applicants is drawn to the *Freedom of Information Act 1982* (Cth) (FOI), which gives members of the public right of access to documents in the possession of the Commonwealth and its agencies.
- 33.2 The Act extends as far as possible the right of the community to access information (generally documents) in the possession of the Commonwealth, limited only by exceptions and exemptions necessary for the protection of essential public interests and the private and business affairs of persons in respect of whom information is collected and held by Departments and public authorities.
- 33.3 Rights of access also exist under other legislation, including the *Ombudsman Act 1976* (Cth). Courts also have legal rights to access a wide range of information.
- 33.4 Applicants should also be aware of the *Australian Information Commissioner Act 2010* (Cth), which established the Office of the Australian Information Commissioner to perform freedom of information, privacy and information policy functions.

34. PRIVACY

- 34.1 Applicants are advised that it is Commonwealth policy to ensure that there is no loss of privacy protection when a Commonwealth entity contracts for the delivery of services.

- 34.2 Without limiting any obligations under the *Privacy Act 1988* (Cth), Applicants who are selected as a result of this process are required, under the Deed, to agree not to do an act, or engage in a practice, that would breach an Australian Privacy Principle under the *Privacy Act 1988* (Cth) if done or engaged in by a Commonwealth entity to which the Australian Privacy Principles apply. Applicants selected as a result of this process will also need to agree to impose those same obligations on any Subcontractor engaged by the Applicant.

35. WORKPLACE GENDER EQUALITY

- 35.1 Commonwealth policy prevents the Department from entering into contracts with Applicants who are non-compliant under the *Workplace Gender Equality Act 2012* (Cth) (the WGE Act).
- 35.2 Appointed Applicants should note that if during the term of the Deed, the successful Applicant becomes non-compliant with the WGE Act, the Applicant must notify the Department's contact officer.
- 35.3 For further information about coverage of the WGE Act, contact the Workplace Gender Equality Agency on (02) 9432 7000.

36. WORK HEALTH AND SAFETY

- 36.1 The Department acts in strict compliance with its obligations under the Work Health and Safety Act 2011 (Cth) (WHS Act) in relation to the maintenance of a safe workplace and safe systems of work.
- 36.2 Applicants will be required to act in such a way as to not by action or omission place the Department in breach of its obligations under the WHS Act. Applicants should be aware that they may also have their own obligations under the law in relation to these matters with which strict compliance will be required.

37. ANTI-TERRORISM

- 37.1 Applicants' attention is drawn to the obligations under Part 4 of the Charter of United Nations Act 1945 (Cth) and the Charter of United Nations (Dealing with Assets) Regulations 2008 (Cth). These laws require any person who holds assets or funds belonging to a person or organisation on the list of persons and entities designated as terrorists to immediately freeze those assets. It is an offence to make any funds or assets available to a person or organisation on the list. The list and more information are available at http://www.dfat.gov.au/icat/UNSC_financial_sanctions.html
- 37.2 The Department will not enter into a Contract with a person or organisation on the list.

38. ANTI-MONEY LAUNDERING

- 38.1 Applicants must comply with any obligations applicable to them contained in the Anti-Money Laundering and Counter-Terrorism Financing Act 2006 (Cth).

39. ILLEGAL WORKERS

- 39.1 It is Commonwealth policy not to contract with providers engaging Illegal Workers.

40. INDIGENOUS PROCUREMENT POLICY

- 40.1 It is Commonwealth policy to stimulate Indigenous entrepreneurship and business development, providing Indigenous Australians with more opportunities to participate in the economy (see Indigenous Procurement Policy at www.dpmc.gov.au/ipp for further information).

PART 6 - STATEMENT OF REQUIREMENT

1. BACKGROUND

- 1.1 The Community Service Obligation (CSO) Funding Pool was established on 1 July 2006 under the Fourth Community Pharmacy Agreement and continued under the Fifth and Sixth Agreements.
- 1.2 The primary objective of the CSO Funding Pool is to ensure that arrangements are in place to provide all Australians with ongoing and timely access to PBS Medicines via their Community Pharmacy. The CSO Funding Pool provides support to pharmaceutical wholesalers supplying PBS Medicines (as defined under the CSO) to community pharmacies across Australia, regardless of pharmacy location and the relative cost of supply.
- 1.3 As part of the Sixth Agreement, it was announced that from 1 July 2016 Distributors would also be required to provide NDSS Distribution Services to Distribution Points, for on supply to Registrants under the NDSS.

2. PARTICIPATION

- 2.1 The objective of this ITA is to identify organisations that could be eligible to participate as Distributors.
- 2.2 Distributors can be:
- national; or
 - state based.
- 2.3 The Department will decide, at its absolute discretion, the number of Distributors to be appointed from this ITA process.
- 2.4 Distributors cannot access, by this Deed or any other arrangement, both the National CSO Funding Pool and the State Based CSO Funding Pool simultaneously. This applies to any entities engaged by the Distributor, as a subcontractor or otherwise, in connection with the Deed.
- 2.5 Applicants for the state based CSO Funding Pool are able to submit a single Application for more than one state or territory. Applicants must clearly state which State/s and/or Territory/ies they are submitting for.
- 2.6 All Applicants, including any existing Distributors, who wish to be considered for appointment from 1 January 2017, **must** complete and lodge an Application containing all information required by this ITA.
- 2.7 All Applicants must hold the Licences and Certificates related to the Services, as applicable to each State and/or Territory of Australia.
- 2.8 Applicants that are already supplying services in accordance with the CSO Deed and Operational Guidelines must demonstrate how they will continue to deliver services from 1 January 2017.

- 2.9 Applicants that are not already supplying services must demonstrate how they propose to comply with the CSO Operating Guidelines from 1 January 2017 or, where compliance is not possible (acting reasonably) on or before the end of the Transition Period which is 1 April 2017.

3. COMPLIANCE WITH CSO OPERATIONAL GUIDELINES

- 3.1 The CSO Operational Guidelines set out, amongst other things, the Compliance Requirements and Service Standards which are summarised below. More specific details of the Compliance Requirements and Service Standards can be found in the Draft Deed and CSO Operational Guidelines provided in this ITA.

CSO Compliance Requirements

- 3.2 To meet their obligations under the CSO Compliance Requirements, Distributors must:
- a. Provide a single entry point for Distribution Points to order CSO Products, receive information and resolve queries;
 - b. Maintain access to established infrastructure and sufficient financial capacity to meet the CSO Compliance Requirements and Service Standards; and
 - c. Maintain the quality of CSO Products that they supply, including meeting all applicable storage condition requirements, holding all necessary State and Territory licences, and complying with the *Code of Good Wholesaling Practice for Medicines* in Schedules 2, 3, 4 and 8 (1 April 2011).

CSO Service Standards

- 3.3 In addition to the three CSO Compliance Requirements, Distributors must also:
- a. Supply any PBS Medicine;
 - b. Supply any NDSS product;
 - c. Supply any PBS Medicine at or below the Price to Pharmacist, or Claimed Price plus the Wholesale Mark-up;
 - d. Supply any NDSS Product at no cost to the Access Point;
 - e. Supply any Low Volume PBS Medicine and ensure that they meet the set Threshold for Sales of Low Volume PBS Medicines;
 - f. Supply PBS Medicines to any Community Pharmacy and ensure that they meet the set Threshold for Sales to Rural and Remote Community Pharmacies;
 - g. Supply PBS Medicines within the Guaranteed Supply Period (72 hours from the Regular Order Cut Off Time for medicines listed on the High Volume List or 24 hours from the Regular Order Cut Off Time for Low Volume PBS Medicines) and make available a Daily delivery service to Community Pharmacies;
 - h. Supply any product listed on the NDSS Product Schedule from the Regular Order Cut Off Time within the Guaranteed Supply Period of 24 hours; and
 - i. Stock in its warehouses or distribution centres at least one Brand of each CSO Product. For multi branded PBS Medicines, the Distributor must hold Stock of at least one Innovator Brand and one additional brand which is Benchmark Priced.

4. TERM OF THE DEED

- 4.1 The Deed between the Commonwealth and the Distributor comes into effect on signature by the Commonwealth and the Distributor and commences operation on 1 January 2017, or such other date as agreed in writing by the parties, whether it is signed before or after that date and ending on 30 June 2018.
- 4.2 The Commonwealth may, by notice in writing to the Distributor, extend this Deed:
- until the expiration of the Sixth Agreement on 30 June 2020; and
 - after the expiration of the Sixth Agreement, for two successive periods of not more than 12 Months each.
- 4.3 The Commonwealth may, by notice in writing to the Distributor, and at any time during the Term, vary the Deed to ensure that it at all times remains consistent with the Sixth Agreement.

5. OPERATIONAL ENVIRONMENT

- 5.1 The Distributor must be willing to cooperate with, and operate in, an environment comprised of other contracted service providers to the Commonwealth, such as the CSO Administration Agency and the NDSS Administrator.

CSO Administration Agency

- 5.2 The Administration Agency is an independent entity that reports to the Department. The Administration Agency provides administration functions over the supply of PBS Medicines and NDSS Products. Its functions include, but are not limited to:
- a. assessing payment claims by the Distributors in relation to PBS Medicines and allocating the CSO Funding Pool on the basis of approved claims;
 - b. calculating only the Supply Component of Payments in relation to NDSS Distribution Services based on information from the NDSS Administrator;
 - c. ensuring the ongoing compliance of the Distributors with all of their obligations, including the CSO Compliance Requirements and Service Standards;
 - d. implementing a system for receiving and resolving Complaints; and
 - e. providing a Help Desk service for the Distributors to receive information on matters such as Payments and the provision of Data and Reports.
- 5.3 The Administration Agency will also monitor the performance of Distributors by conducting site audits of the warehouses and storage facilities used by each Distributor to store their CSO Products. These audit visits will enable the Administration Agency to ensure that Distributors are meeting the CSO Compliance Requirements and Service Standards under the Deed.

NDSS Administrator

- 5.4 The NDSS Administrator is an independent entity that reports to the Department.
- 5.5 The NDSS Administrator cooperates in good faith with the Administration Agency only in respect of NDSS Distribution Services and not PBS medicines. Its functions for the Distributors include, but are not limited to:

- a. liaising with Distributors, to the extent permitted under the Deed, in relation to queries Distributors have about the NDSS Distribution Services;
- b. calculating the Direct Cost and Delivery Components of NDSS Payments based on number of products delivered and cost of products;
- c. providing information to the CSO Administration Agency about the numbers of NDSS Products delivered to enable the Agency to calculate the Supply Component;
- d. deducting sanctions as approved by the CSO Administration Agency;
- e. participating in the complaints procedure forming part of the CSO Deeds as required to properly administer the NDSS; and
- f. oversee, maintain and support the ordering gateway for Access Points to order and receive NDSS Products from Distributors.

6. GENERAL OBLIGATIONS OF THE DISTRIBUTOR

6.1 The Distributor:

- a. acknowledges that there may be other Distributors receiving payments from the CSO Funding Pool and NDSS Distribution Service;
- b. agrees and accepts that the Commonwealth is solely responsible for determining the amount of funding and the calculation of payments for each year as permitted by the Deed; and
- c. agrees at all times to act ethically and in good faith towards the Commonwealth and the Administration Agency in the performance of its obligations under the Deed.

6.2 The Distributor must:

- a. allow the Administration Agency and the NDSS Administrator to perform all necessary functions for the proper administration of the CSO Funding Pool and the NDSS Administration Services;
- b. fully cooperate by providing any information or data, including Data and Reports in accordance with the Deed reasonably required by the Administration Agency or the Commonwealth in a timeframe specified by the Administration Agency or the Commonwealth;
- c. comply with any Business Plan, Remedial Business Plan and/or Business Continuity Plan developed by the Administration Agency or the Commonwealth in accordance with the requirements in the Deed;
- d. comply with any audit or review requirements of the Administration Agency, the Australian National Audit Office, the Auditor-General, the Privacy Commissioner, the Australian Information Commissioner and the Commonwealth or its authorised representative; and
- e. ensure that any Data, Reports or information provided for any purpose, to any of the entities, is accurate and complete.

7. REPORTING REQUIREMENTS

- 7.1 The Distributor will be required to provide Reports at the times and in the format as specified in the Deed or CSO Operational Guidelines or as reasonably directed by the Administration Agency.
- 7.2 The Distributor must provide any other Data and Reports required for activities contained within this Deed and Operational Guidelines, including audits and Reviews of the CSO Funding Pool.

8. EVALUATION AND MONITORING REQUIREMENTS

- 8.1 The Distributor must ensure that it meets the requirements of the Deed regarding subcontracting. In particular, the Distributor must remain completely responsible for the performance of any subcontractor against all relevant CSO Deed Obligations for which the subcontractor is being engaged.
- 8.2 The Distributor must allow access to the Administration Agency to undertake a range of ongoing monitoring and auditing activities, including regular site visits to Distributors' head office and distribution centres for the purpose of ensuring the Distributor is meeting its obligations.

9. PAYMENT ARRANGEMENTS

- 9.1 The Commonwealth's payment obligations under the Deeds will be conditional upon there being an appropriation by Parliament in respect of the CSO Funding Pool and the NDSS.
- 9.2 The Commonwealth may vary the total amount of the CSO Funding Pool for any Year during the Term of the Deed (by reducing or increasing it) and will notify Distributors before the commencement of each Year of the total value of the CSO Funding Pool for the next Year. The Commonwealth will not exercise its right to reduce the total amount of the CSO Funding Pool to zero. This clause does not limit the Commonwealth's other Rights including in respect of payments under the Deeds.
- 9.3 Payments will be made from the CSO Funding Pool to Distributors that meet their Obligations under the Deeds, including the CSO Compliance Requirements and Service Standards.
- 9.4 Payments will be made for NDSS Distribution Services to Distributors that meet their Obligations under the Deeds, including the CSO Compliance Requirements and Service Standards.
- 9.5 The Administration Agency may adjust Payments to the Distributor in situations including, but not limited to, where audits of Reports or Data identify inaccuracies in calculations that must be corrected. Payment adjustments will not be used as a Sanction for Distributor Non-Performances. If the Administration Agency deems it necessary to impose a financial consequence for a Non-Performance, the financial Sanction provisions as set out in the Deed will be used.
- 9.6 **CSO payments** will be calculated by:
- a. the Administration Agency (the Administration Agency is responsible for determining which sales are relevant to specific obligations); and
 - b. paid monthly in arrears to Distributors by the Department in accordance with the Deed.

- 9.7 **NDSS payments** will be calculated by:
- a. the NDSS Administrator (in relation to the direct cost and delivery component);
 - b. the Administration Agency (in relation to the supply component); and
 - c. paid monthly in arrears to Distributors by the Department in accordance with the Deeds.
- 9.8 By 31 August in each Year, the Administration Agency will perform a final reconciliation of all Data submitted and Payments received from the Distributor in the preceding year;
- 9.9 Where the annual reconciliation identifies inaccuracies in calculations that must be corrected, the Administration Agency may:
- a. adjust payments made to the Distributor for the Year of the reconciliation; and
 - b. apply financial or non-financial sanctions for any non-performance.
- 9.10 The reconciliation and assessment will be the final determination of payments payable to the Distributor for that Year.

10. INSURANCE REQUIREMENTS

- 10.1 Applicants should have, or be prepared to obtain if engaged, for so long as any obligations remain in connection with the Deed, the following levels of insurance in place (refer to the attached Deed clauses referring to insurance and indemnity):
- a. appropriate workers compensation insurance, as required by Law;
 - b. public liability insurance and products liability insurance on an occurrence basis for an insured amount of not less than \$20 million per occurrence; or
 - c. public liability insurance and products liability insurance of \$20 million in the aggregate where there is a right to reinstate \$20 million following a claim; and
 - d. professional liability or errors and omissions insurance for an insured amount of not less than \$10 million for each and every Loss.

PART 7 - GLOSSARY

Term	Definition
Access Point	means any Community Pharmacy or other organisation appointed by the NDSS Administrator or the Commonwealth to supply NDSS Product to registrants under the NDSS
ACT	Australian Capital Territory
Administration Agency	means any one or more service providers contracted by the Commonwealth to administer the supply of PBS Medicines and NDSS Products.
Applicant	means an entity that submits a Application, and includes a potential Applicant
Application	means a response submitted by an Applicant to this ITA
Assessment Criteria	means the criteria set out in this ITA that will be used to evaluate the Applications received
Closing Time	means the closing time and date of this ITA as specified at Part 1, clause 7.1 of this ITA
Commonwealth	means the Commonwealth of Australia
Community Pharmacy	means the group of pharmacies approved to supply PBS subsidised medicine, in accordance with section 90 of the <i>National Health Act 1953</i>
Confidential Information	means information (whether or not owned by the Commonwealth) that: <ul style="list-style-type: none"> (a) is by its nature confidential; or (b) the receiving party knows or ought to know is confidential, (c) but does not include information which: <ul style="list-style-type: none"> a. is or becomes public knowledge other than by breach of the Deed; b. is in the possession of a party without restriction in relation to disclosure before the date of receipt; or c. has been independently developed or acquired by the receiving party
Contact Officer	means the contact person for all matters pertaining to this ITA process,

Term	Definition
	as identified at Part 1, clause 5 of this ITA
CSO	means Community Service Obligation
CSO Compliance Requirements	means the requirements as set out in the CSO Operational Guidelines at Schedule 3 to this ITA
CSO Funding Pool	means the Commonwealth funding made available to Distributors under the CSO arrangements of the Sixth Agreement
CSO Jurisdiction	means the jurisdiction(s), either National or State Based, in which the Distributor is accessing the CSO Funding Pool
CSO Products	means PBS Medicines and NDSS Products
CSO Service Standards	means the requirements in CSO Operational Guidelines at Schedule 3 to this ITA
Data	means the data that meets the requirements specified in the Draft Deed
Deed	means a deed between the Department and appointed Applicant(s)
Department	means the Department of Health
Distribution Point	means: (a) for PBS Medicines means Community Pharmacies; and (b) for NDSS means Access Points
Distributor	means an entity that has been engaged by the Commonwealth to provide services to access the CSO Funding Pool and provide the NDSS Distribution Services and has entered into a Deed with the Commonwealth
Draft Deed	means the document attached as Schedule 2 to this ITA
Guaranteed Supply Period	means: (a) for PBS Medicines on the High Volume List, within 72 hours from the Regular Order Cut Off Time; (b) for all other PBS Medicines (including Low Volume PBS Medicines), within 24 hours from the Regular Order Cut Off Time; and (c) for NDSS Products, within 24 hours from the Regular Order Cut Off Time.
Illegal Worker	means a person who:

Term	Definition
	<p>(a) has unlawfully entered and remains in Australia;</p> <p>(b) has lawfully entered Australia, but remains in Australia after his or her visa has expired; or</p> <p>(c) is working in breach of his or her visa conditions</p>
ITA	means this Invitation to Apply
National Diabetes Services Scheme (NDSS)	means the Commonwealth's scheme to ensure that persons with diabetes have timely, reliable and affordable access, on a national basis, to the supplies and services required for the effective self-management of their condition
NDSS Administrator	means any one or more service providers contracted by the Commonwealth to access and monitor the supply of NDSS Products.
NDSS Distribution Services	means the supply of diabetes related products for the purposes of the NDSS on the terms of the Service Standards and Compliance Requirements
NDSS Products	means all items listed on the NDSS Product Schedule or in a written determination made by the Minister for Health
PBS Medicine	means all items listed on the Schedule of Pharmaceutical Benefits (see Glossary in CSO Operational Guidelines for items not included)
Regular Order Cut Off Time	means the Daily time, as agreed by the CSO Distributor and the Community Pharmacy, by which orders must be lodged with the CSO Distributor.
Rural and Remote Locations	means a location that has been defined as a Rural and Remote Location in the CSO Operational Guidelines
Schedules	means all or any of the schedules to this ITA
Services	means the services and activities described in the Statement of Requirement, the Draft Deed and the CSO Operational Guidelines.
Sixth Agreement	means the Sixth Community Pharmacy Agreement between The Honourable Sussan Ley, MP, Minister for Health and Aged Care and Minister for Sport on behalf of the Commonwealth of Australia and the Pharmacy Guild of Australia
State Based	means any, but not all, Australian States and Territories
Statement of Requirement	means the description of the Services as set out in Part 6 of this ITA

Term	Definition
Subcontractors	means an entity that contracts to provide goods or services to the successful Applicant(s) in order for the Applicant to meet obligations under the resultant Deed
Transition Period	means the period from 1 January 2017 to 1 April 2017
Year	means a financial year from 1 July to 30 June

SCHEDULE 1 – APPLICANT RESPONSE SCHEDULE

The **Applicants Response Schedule** has been provided as a separate document.

SCHEDULE 2 - DEED OF AGREEMENT

The **Deed of Agreement** has been provided as a separate document.

SCHEDULE 3 - CSO OPERATIONAL GUIDELINES

The **CSO Operational Guidelines** has been provided as a separate document.