

PHARMAC

Pharmaceutical Management Agency

External Tender System

High Level Business Requirements

January 2016

1 Document Control

1.1 Related Documents

| Document Name | Version | Author | Description | Objective ID/ Link |
|---|---------------|---------------|---|---|
| PHARMAC Invitation to Tender (ITT) | 6 Nov 2015 | PHARMAC | Invitation for the supply of certain pharmaceuticals to DHB hospitals and/or to community pharmacies in New Zealand | https://www.pharmac.health.nz/news/tender-2015-2016/ |
| Government Security Classifications | Current | NZ Government | Security classifications | https://protectivesecurity.govt.nz/home/information-security-management-protocol/new-zealand-government-security-classification-system/ |

1.2 Government Standards and Tools

The following standards and compliance tests may apply to this solution.

| Standard Name | Version | Compliance Required | Link |
|---------------------------------------|---------|---------------------|---|
| Government Web Accessibility Standard | 1.0 | TBC | https://webtoolkit.govt.nz/standards/web-accessibility-standard-1-0/ |
| Government Web Usability Standard | 1.2 | TBC | https://webtoolkit.govt.nz/standards/web-usability-standard-1-2/ |
| Risk Assessment | Current | TBC | https://webtoolkit.govt.nz/guidance/testing-and-assessment/web-standards-risk-assessment/ |
| NZISM | Current | TBC | http://www.gcsb.govt.nz/news/the-nz-information-security-manual/ |
| Requirements for Cloud Computing | Current | TBC | https://www.ict.govt.nz/guidance-and-resources/information-management/requirements-for-cloud-computing |
| Rules of Sourcing | Current | Full | http://www.business.govt.nz/procurement/for-agencies/key-guidance-for-agencies/the-new-government-rules-of-sourcing |
| Records Management | Current | TBC | http://archives.govt.nz/records-management-standard-new-zealand-public-sector-downloads |

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3 Overview

3.1 Document Purpose

The purpose of the requirements specification is to document the requirements of PHARMAC for selecting a solution to meet our tender management requirements. This document will be used by members of the project team to help select an appropriate solution for implementation, as well as to verify the correct functioning of the system.

3.2 Purpose of the Project

3.2.1 Background

The annual multi-product tender is a mechanism used by PHARMAC to procure supply of pharmaceuticals for community pharmacies and/or DHB hospitals.

The tender is open from approximately the beginning of November until the end of December, involving approximately 50-60 suppliers, and 500-600 medicines and/or medical devices (tender items).

The tender uses a sealed bid process; due to this suppliers are encouraged to put their best bids forward. The tender results in significant cost saving, which frees up expenditure to be invested in new treatments.

In the future the scope of the tenders may be extended to include the procuring supply of some medical devices to DHB hospitals. In addition, multiple tenders maybe run each year, including some simultaneously.

3.2.3 Future State

A solution is required to run PHARMAC's tender processes for pharmaceuticals (and potentially medical devices), which includes recording and managing tender bids and relevant tender bid information received during PHARMAC's tenders. The solution needs to allow data exports to PHARMAC systems. Evaluation of tender bids is done using PHARMAC internal systems.

The solution needs to satisfy the requirements of PHARMAC, with a focus on both security and usability of the solution by external suppliers (domestic and international). The solution is also required to meet New Zealand Government Standards.

It must be obvious to pharmaceutical suppliers that this solution is secure and independent from PHARMAC control. This is to ensure suppliers are aware that bids are private to their organisation while the tender is open and that PHARMAC can only view these bids after the tender closes. One way to demonstrate this independence is to provide a hosted solution where the security controls specified in this document are verified and enforced by a third party (which could be the solution provider). The solution must be outside the technical control of PHARMAC.

We suggest reviewing Appendix A: Glossary of Terms and Appendix B: Screen flow before reading this document.

3.2.4 Goals/ Outcomes of the Project

- Ensure tender bids and relevant tender bid information is accurately recorded and presented to PHARMAC in a consistent manner.
- Improve supplier confidence in PHARMAC and the tender process.
- Reduce the administrative workload of PHARMAC staff by removing the need to manually follow up with suppliers for additional details and information for their tender bids.
- Reduce user error and data loss by suppliers.
- Reduce time spent fixing supplier mistakes made during the tender bids.
- Ensure the data provided is designated to particular tender bids.

PHARMAC would also consider alternative ways to meet our business requirements, even if they do not fit within the precise definitions in this requirements document.

3.2.5 Supplier Services

As PHARMAC has no access to tender bids during the tender process it may be beneficial to have end user support available to users from the supplier.

During critical periods of PHARMAC tenders it would be very useful to be able to schedule conversations with the solution provider during NZ business hours.

The solution provider must be able to provide support during New Zealand business hours for specified, pre-arranged periods. For example, this is expected to be required for 1-3 days per year, at the end of the period the PHARMAC annual tender is open.

Please note the SLAs in the non-functional requirements, section 6.3.7 Service Level Requirements.

3.4 Users of Product

The following people will be the key users of the product.

| User | Responsibility |
|---------------|--|
| PHARMAC Staff | Administer and set up tenders. |
| Supplier | Start, review, complete and submit tender bid. |

4 Scope

4.1 In Scope (Systems, Processes)

Existing systems and processes to consider:

| Process/ System | Description |
|---|--|
| PHARMAC Internal Tender System | PHARMAC's tender system used for storage and reporting for the purposes of tender evaluation and awarding contracts. |
| PHARMAC Internal Medical Devices System | PHARMAC's medical devices system. |
| MBIE Government Rules of Sourcing | Rules for government procurement. |
| PHARMAC Invitation to Tender (ITT) | PHARMAC's Invitation to Tender for the multi-product tender. |
| New Zealand Information Security Manual (NZISM): comply with baseline technical security standards. | Baseline technical security standards for government departments and agencies. |
| Requirements for Cloud Computing | New Zealand Government's requirements for cloud computing. |
| Government Web Accessibility Standard | New Zealand Government's accessibility-specific requirements. |
| Government Web Usability Standard | The Standard sets minimum content and other requirements to help people use a site and its contents. |

4.2 In Scope (Deliverables)

Provide a list of the project's high-level deliverables, approximately in the order of priority from greatest to least.

| Description | Priority |
|--|----------|
| A solution to record and manage tender bids and relevant tender bid information received during PHARMAC's multi-product tenders. | Must |
| Provision to host or provide the solution on behalf of PHARMAC. | Must |
| The solution is to provide functions as listed in section 6 'Business Requirements'. | Must |
| The solution is to provide non-functional requirements as listed in section 6.3 'Non-Functional Requirements'. | Must |
| Transfer function: to export data from the solution to PHARMAC systems. | Must |
| Solution testing, including functional, performance, and security testing. User acceptance test will be done by PHARMAC. | Must |
| Functional, performance, and security testing results / reports. | Must |
| A digital, on-line user guide or manual, to instruct users how to use the system. | Must |
| The provision of PHARMAC and end user support as outlined in section 3.2.5 Supplier Services. | Must |

4.3 Out of Scope

Provide a list of any issues or requests that will not be addressed by this project.

| Description | Reason for Exclusion |
|-------------------------|---|
| Business process change | Any changes to processes that are not part of the process for selecting and implementing the solution itself. |

5 Key Assumptions, Dependencies and Constraints

5.1 Assumptions

| ID | Assumptions | Who |
|----|--|------------------------------------|
| A1 | All reporting for the purposes of tender evaluation and accepting Tender Bids (contracts) will be done using PHARMAC systems. | Procurement & Contracts team (P&C) |

5.2 Dependencies

| ID | Dependencies | Who |
|----|--|-----|
| D2 | Alignment with the restraints around bidding as part of the PHARMAC Invitation to Tender document (see 1.1 section). | P&C |

5.3 Constraints

| ID | Constraints | Who |
|----|--|-------------------|
| C1 | Compliance with the Government Rules of Sourcing (refer to Government Standards and Tools section above). | P&C |
| C2 | <p>Solution meets specified requirements in the New Zealand Information Security Manual (NZISM) v2.4 (refer to Government Standards and Tools section above). Note that you must meet requirements marked "System Classification(s): All Classifications; Compliance: MUST" in specified sections unless otherwise noted. Relevant NZISM sections in version 2.4 include:</p> <ul style="list-style-type: none"> • 6.1.6.C.01, 6.2.4.C.01, 6.2.5.C.01 • 7 • 11 • 14.1.8 • 14.5 (System Classification(s): All Classifications; Compliance: MUST AND SHOULD) • 16.1, 16.3, 16.5 (System Classification(s): All Classifications; Compliance: MUST AND SHOULD) • 17 • 18.4, 18.5 • 19.1.10, 19.1.12, 19.3.8 • 20.1.9, 20.3.4, 20.3.5, 20.3.10, 20.4.4 | ICT Services team |
| C3 | Compliance with government accessibility and usability standards | ICT Services team |

6 Business Requirements

The following sections document the various business requirements of this project.

MOSCOW Prioritisation Categories

Must Have

A “Minimum Usable SubseT” (MUST) of requirements which the project guarantees to deliver. Without these the solution would not be viable/legal/secure. If there is any possible workaround, technical or manual, then it is a “Should Have” or “Could Have” requirement. Categorising a requirement as a Should Have or Could Have does not mean it won’t be delivered; simply that delivery is not guaranteed.

Should Have

Should Have requirements are defined as:

- important but not vital
- may be inconvenient to leave out, but the solution is still viable
- may need some kind of workaround, e.g. management of expectations, some inefficiency, an existing solution, paperwork etc. The workaround may just be a temporary one

One way of differentiating a Should Have requirement from a Could Have is by reviewing the degree of inconvenience caused by the requirement not being met, measured in terms of business value or number of people affected.

Could Have

Could Have requirements are those that are wanted or desirable but less important, or have less impact if left out compared with a Should Have.

Could Have requirements provide the main pool of contingency, since they would only be delivered in their entirety in a best case scenario. When a problem occurs and the deadline is at risk, one or more of the Could Haves provide the first choice of what is to be dropped from a timebox.

Won’t Have (this time)

These are requirements which the project team have agreed will not be delivered within this timebox. At the start of a project, the first timebox will have the majority of requirements under this category.

6.1 High Level Business Requirements

| ID | Description | Priority | Source | Comments |
|---------|--|----------|--------|----------|
| HLR-000 | <p>The solution must be outside the technical control of PHARMAC.</p> <p>Rationale: <i>It must be obvious to suppliers that this solution is secure and independent from PHARMAC control. This is to ensure suppliers are aware that Tender Bids are private to their organisation while the tender is open and that PHARMAC can only view these Tender Bids after the tender closes. One way to demonstrate this independence is to provide a hosted solution where the security controls specified in this document are verified and enforced by a third party (which may or may not be the solution provider).</i></p> | Must | P&C | |
| HLR-001 | <p>The solution shall contain multiple data fields for storing the details of tenders, Tender Bids and associated information received during PHARMAC tenders².</p> <p>Specifically data fields defined section 10.1.1- 10.1.6 of this document.</p> <p>Provide a mechanism to upload relevant tender information³ relating to a Tender Bid for a specific Tender Item entered by a supplier.</p> <p>These fields should be customisable by the solution provider to allow the ability to input data related to the tender.</p> | Must | P&C | |
| HLR-002 | <p>The solution shall allow suppliers (users and approvers) the ability to enter in Tender Bids within multiple Product Groups at the Tender Item level⁴.</p> <p>Suppliers should be able to submit multiple Tender Bids on a Tender Item.</p> | Must | P&C | |
| HLR-003 | <p>The solution must have visual cues to alert the user if mandatory fields if a Tender Bid on a Tender Item has been started but not been completed.</p> | Must | P&C | |

² PHARMAC's main tender (Approximately beginning November – end December), but other tenders are possible in the future

³ Maximum file size of 25megabytes; PDF, Word (.doc, .docx), excel spreadsheets (.xls, .xlsx), pictures (.jpg, jpeg, etc)

⁴ Refer to Appendix F for data model and Appendix A for Glossary of Terms

| ID | Description | Priority | Source | Comments |
|---------|---|----------|--------|----------|
| HLR-004 | The solution shall provide a page or report to enable suppliers to identify Tender Bids where some information has been entered but one or more mandatory fields for that record type are empty. | Must | P&C | |
| HLR-005 | The solution shall provide the facility for PHARMAC staff administrators to export all registered user details from the system. | Must | P&C | |
| HLR-006 | <p>The solution shall provide the ability for suppliers to print and view all Tender Bids including Tender Bids statuses (complete/incomplete). This would ideally be implemented as a report that can be run by users. Pages where information is entered should also print cleanly.</p> <p>This functionality shall be maintained when the tender has closed, for a specified period of time – initially set at 30 days.</p> <p>Rationale: All reports and screens are printable to allow suppliers to review their draft Tender Bids and information before and after submitting their Tender Bids.</p> | Must | P&C | |
| HLR-007 | <p>The solution must contain an administration function to allow creation and amendment of tenders by PHARMAC, before and during a tender.</p> <p>The solution could provide the facility to notify suppliers associated with the tender in question of the amendment.</p> <p>Rationale: PHARMAC shall have the ability to amend particular Tender Items and end date & time of the tender.</p> | Must | P&C | |
| HLR-008 | <p>Tenders shall have a start and end date and time indicating the applicable time zone.</p> <p>Rationale: PHARMAC will set the start and end dates and times for when the tenders will open and close.</p> | Must | P&C | |
| HLR-009 | PHARMAC has no access to the Tender Bids and associated information whilst | Must | P&C | |

| ID | Description | Priority | Source | Comments |
|---------|---|----------|--------|----------|
| | <p>the tenders are open. Appropriate controls should be in place to prevent PHARMAC and solution providers from accessing Tender Bid information while the tender is open.</p> <p><i>Rationale: Commercially sensitive information entered while the tender is still open is not subject to bias or unfairness by PHARMAC.</i></p> | | | |
| HLR-010 | <p>There must be a testing or pre-production environment. This environment should be a mirror of the live environment. The environment must be clearly marked, and efforts should be to ensure the environments cannot be mistaken – for example a different background colour.</p> <p><i>Rationale: All changes, testing and troubleshooting by the solution provider should be completed in the pre-productive (test) environment before migrating the change(s) to the production (live) environment.</i></p> | Must | P&C | |
| HLR-011 | <p>The solution shall contain a search function to allow suppliers to search for a Product Group⁶. The solution could allow suppliers to search for Tender Items⁶.</p> <p>This search should search all text fields/fields specified in the data model.</p> <p><i>Rationale: the search function should allow suppliers to easily search for product groups which suppliers wish to submit/amend/review tender bids for instead of scrolling through a large list of product groups.</i></p> | Must | P&C | |
| HLR-012 | <p>The solution shall provide a mechanism for PHARMAC to upload Product Groups and Tender Items for each tender. There can be multiple uploads, and tender items can also be added or edited individually using the solution.</p> <p>Upload formats: CSV (preferred) & XML (option)</p> <p><i>Rationale: PHARMAC will upload the Product Group and Tender Item list, for the purposes of populating the Tender Item list fields. Manual entry for all tender items is impractical given the expected tender sizes.</i></p> | Must | P&C | |

| ID | Description | Priority | Source | Comments |
|---------|---|---------------|--------|----------|
| HLR-013 | <p>The solution could provide a mechanism for PHARMAC to upload supplier organisation details and user details for the tenders.</p> <p>Upload formats: CSV (preferred) & XML (option)</p> <p>Rationale: PHARMAC will upload the supplier list, for the purposes of populating the supplier information fields.</p> | Could | P&C | |
| HLR-014 | <p>The solution shall provide a facility for suppliers to save Tender Bids where all mandatory fields are not completed.</p> <p>Rationale: This enables suppliers to add information when it comes available.</p> | Must | P&C | |
| HLR-015 | <p>The solution shall provide means to deliver intuitive help text with appropriate guidance. This should include context sensitive help and must include a user guide. The user guide is to be provided by the solution provider – this guide is to be available and accessible through the solution.</p> <p>Rationale: Bubble or hover text will assist the user to understand terms or purpose of fields. A link to a user guide or manual should be available from the solution.</p> | Should / Must | P&C | |
| HLR-016 | <p>The solution shall provide a mechanism to allow PHARMAC and suppliers (users and approvers) to create and manage their own account details and passwords via the solution. Please see detailed functional requirements (6.2.2 Registration Requirements) below for further information.</p> | Must | P&C | |
| HLR-017 | <p>The solution shall contain a password recovery function to allow users to recover their login details.</p> | Must | P&C | |
| HLR-018 | <p>PHARMAC could have the ability to delete all information for an individual tender, for all tenders, supplier, or user information in the solution at any point in time. There should be extensive safeguards to prevent accidental use of this function.</p> <p>The solution provider should be able to delete all data at PHARMACs request at any point in time.</p> | Could | P&C | |

| ID | Description | Priority | Source | Comments |
|---------|--|----------|--------|----------|
| HLR-019 | The solution could contain a filter function to allow Product Group to be viewed by Categories (ie Category 1, Category 2, and Category 3) on the Product Group List screen (see section 8.1 Screen Flow for Bidding). | Could | P&C | |
| HLR-020 | <p>The solution could provide a mechanism to allow for rebates and/or other pricing arrangements (for example tiered pricing). This feature should be able to be enabled or disabled for each individual tender.</p> <p>Rebates and/or other pricing arrangements could be implemented by allowing suppliers to upload a document describing the rebates and/or other pricing arrangements offered in their tender bid.</p> | Could | P&C | |
| HLR-021 | The solution could warn a user that they are about to leave a page/screen with unsaved information. | Should | P&C | |
| HLR-022 | <p>The solution could contain an auto save function to automatically save information entered in the solution by suppliers.</p> <p>Rationale: Suppliers are able to recover all or at least some of their information⁵ entered into the solution when responding to a tender in the cases where a power outage occurs, the supplier's system is made unstable by another program, or something goes wrong with the connection to the solution.</p> | Could | P&C | |
| HLR-023 | <p>The solution could contain a time or date based email notification process to alert the relevant supplier roles when a trigger or condition⁶ has been met. Refer to Appendix D: Notifications and Reminders.</p> <p>Rationale: Notifications and specific email content can be configured by PHARMAC by selecting an event/trigger to link to the notification.</p> <p>For example: A supplier's user(s) and approver will receive an email notification to notify them that the tender will be closing 48 hours before the tender is set</p> | Could | P&C | |

⁵ Every 10 minutes

⁶ Refer to Appendix D: Notifications and reminders

| ID | Description | Priority | Source | Comments |
|----|------------------|----------|--------|----------|
| | <i>to close.</i> | | | |

6.2 Functional Requirements

6.2.1 Tender Setup Requirements

| ID | Description | Priority | Source | Comments |
|--------|---|----------|--------|---|
| FR-001 | <p>The solution shall provide PHARMAC staff with the ability to create, view, edit and preview the tenders before opening/releasing the tender to suppliers.</p> <p>Rationale: PHARMAC staff will set up the tenders in the solution before using an internal process to check that the tender as published in the solution reflects what has been approved by PHARMAC. This approval does not require system support, it will be done manually.</p> | Must | P&C | NB: this happens after the existing internal process that approves the tender at a business level. This requirement is simple to ensure that the system reflects the tender that was approved internally. |
| FR-002 | <p>PHARMAC can amend (add, edit and delete) the tender whilst it's open.</p> <p>E.g. change end dates, Product Groups, Tender Items and fields PHARMAC has entered information into.</p> | Must | P&C | |
| FR-003 | The solution could allow PHARMAC to email all the users) from within the solution. This could be limited to users who have are associated with a single tender. | Could | P&C | |
| FR-004 | The solution could provide PHARMAC the ability to notify all suppliers of the changes made to the tender by PHARMAC whilst it's open. | Could | P&C | |

6.2.2 Registration Requirements

| ID | Description | Priority | Source | Comments |
|--------|--|----------|--------|----------|
| FR-030 | The solution shall provide the facility to allow PHARMAC to register suppliers and users and administer user accounts. | Must | P&C | |
| FR-031 | Suppliers should be able to self-register their organisation and their first user, who will be given the approver role. Suppliers will require manual validation / | Must | P&C | |

| | | | | |
|--------|---|-------|--------------|---|
| | activation by PHARMAC before they can view tenders. | | | |
| FR-032 | <p>The solution must provide the facility for suppliers' users with the approver role to register additional users under the supplier.</p> <p>NB: note the security requirements that specify registered suppliers should not be revealed to any supplier. This means that users must be associated with an organisation manually, or that user self-registration is not practical.</p> | Must | P&C | Refer to suggested registration screen flow appendix. |
| FR-033 | The solution shall provide account and/or credential recovery facility to reset user passwords that is both usable and consistent with security best practice. | Must | P&C | |
| FR-034 | Accounts must be locked if the number of login attempts exceeds a given number in a given period of time (initially 5 attempts within 30 minutes). This counter is reset on successful login. | Must | ICT Services | |
| FR-035 | The solution shall provide a facility to allow PHARMAC or the solution provider the ability to unlock locked ⁷ user accounts. | Must | P&C | Accounts are locked manually or through security measures such as brute force password cracking attempts. |
| FR-036 | <p>The solution shall provide a facility that enables PHARMAC to validate and activate non-validated suppliers.</p> <p><i>Rationale:</i> This ensures communication between PHARMAC and the supplier can be established. Enabling PHARMAC to interact with the supplier and ensure they are informed of all relevant information prior to participating in a tender</p> | Must | P&C | Once suppliers are validated they can view and respond to any open tender. |
| FR-037 | It would be beneficial if the solution could provide a form of two factor authentication for user logins. This could be enabled and disabled based on organisation or role. | Could | ICT Services | |
| FR-038 | Suppliers should be able to indicate interest in a tender using the solution; this associates a supplier with a tender, which may facilitate communications and notifications. | Could | P&C | |

⁷ Refer to SEC-007

| | | | | |
|--|---|--|--|--|
| | <p>Tenders should be viewable without indicating interest. Entering Tender Bid information (by entering information into data fields as outlined 10.1.5) automatically indicates interest in a tender.</p> <p>Rationale: Once a supplier has indicated interest the approver and all supplier users associated with a supplier will get any applicable notifications.</p> | | | |
|--|---|--|--|--|

6.2.3 Bidding Requirements (refer to Appendix B: Screen Flows)

| ID | Description | Priority | Source | Comments |
|--------|---|----------|--------|--|
| FR-060 | <p>A supplier shall be able to create a Tender Bid on a Tender Item by entering and storing the details⁸ of their Tender Bids for the Tender Item.</p> <p>Multiple Tender Bids can be made for each Tender Item.</p> <p>Suppliers with the appropriate permissions submit all Tender Bids for all Tender Items at one time. Until the final submission Tender Bids are saved but not submitted individually.</p> | Must | P&C | <p>Refer to diagram 8.1 Screen Flow for Bidding</p> <p>To be clear, all tender bids are submitted at one time by the supplier, by a user with appropriate permissions.</p> |
| FR-061 | Tender Bid details (as defined in section 10.1.5 Tender Bid (Pharmaceutical)) must be stored against each specific Tender Item . | Must | | Refer to diagram 8.1 |
| FR-062 | <p>A Tender Bid/s required Additional Information (As defined in 10.1.6 Additional Information) can be stored against each specific Tender Item but the solution should allow this required Additional Information to be provided at a “Product Group” level or at a “Tender Item” level.</p> <p>For example if all Tender Items a supplier is bidding on under a particular Product Group have the same required Additional Information a supplier can elect to provide this required Additional Information at the Product Group level. However in instances where the Additional Information differs between Tender Items the supplier can elect to put these in at a Tender Item level.</p> | Should | | Refer to diagram 8.1 |

⁸ Refer to section 11.1.4 & 11.1.5

| ID | Description | Priority | Source | Comments |
|--------|---|----------|--------|---|
| FR-063 | <p>The solution must allow PHARMAC to indicate that Tender Bids on individual Tender Items must be made for:</p> <ul style="list-style-type: none"> • Either community or hospital supply (supplier chooses) • Both community and hospital supply (combined Tender Bids) • Just community supply (i.e. no hospital supply) • Just hospital supply (i.e. no community supply) <p>The solution must only allow Tender Bids as per the above.</p> <p>The solution will only enable combined bids to be entered when individual hospital and community Tender Bids have been entered.</p> <p><i>Scenario/condition: if the Tender Item is only available for community sole supply then the supplier must only be allowed to enter a Tender Bid/s for the community market, similarly if the product is only available for hospital sole supply then the supplier must only be allowed to enter a Tender Bid/s for the hospital market and not the community market.</i></p> <p><i>If the product is available for community and hospital supply then the supplier must be allowed to enter Tender Bids for the community and hospital markets.</i></p> | Must | P&C | |
| FR-064 | <p>The solution shall allow fields to be marked mandatory on both Tender Item, Tender Bid details and Additional Information (10.1.5 & 10.1.6 respectively). Fields marked as mandatory must be completed before the Tender Bid can be submitted to PHARMAC by the supplier.</p> <p><i>Rationale: prevents submissions of Tender Bids without required fields being filled in.</i></p> | Must | P&C | |
| FR-065 | <p>The solution shall allow suppliers to enter aggregated Tender Bids.</p> <p><i>Invitation to Tender states: You may, in addition to submitting a separate Tender Bid for each Tender item,</i></p> | Must | P&C | Aggregated tender bid function must be consistent with the PHARMAC Invitation to Tender document. |

| ID | Description | Priority | Source | Comments |
|--------|--|----------|--------|--|
| | <p><i>submit an Aggregated Tender Bid, provided that:</i></p> <p><i>Each Tender Item contained in an Aggregated Tender Bid is a Tender item included in the same Product Group;</i></p> <p><i>You may not aggregate within a single Tender Item (for example, two different brands or pack sizes);</i></p> <p><i>You must also submit a separate Community Tender Bid and/or Hospital Tender Bid, as applicable, for each Tender Item.</i></p> <p>Refer to section 8 “Appendix B: Screen flow” for screen flows</p> | | | |
| FR-066 | <p>Incomplete Tender Bids can be saved with empty mandatory fields.</p> <p>These Tender Bids will be considered “incomplete” and will not be submitted to PHARMAC unless completed. The supplier must be warned of incomplete Tender Bids before submission.</p> | Must | P&C | |
| FR-067 | <p>Mandatory fields are only checked by the solution when submitting Tender Bids, not during entry of Tender Bids. If a supplier attempts to submit Tender Bids with incomplete mandatory fields they should receive a warning that incomplete Tender Bids will not be submitted to PHARMAC.</p> <p>Suppliers must be able to acknowledge that they are willing to progress with the final submission after being warned of incomplete Tender Bids or have the option to go back and complete the incomplete Tender Bids.</p> | Must | P&C | |
| FR-068 | The solution shall provide a facility to allow suppliers to find all incomplete Tender Bids . | Must | P&C | For example a report may be able to be run |
| FR-069 | <p>The solution shall provide a facility for the supplier to indicate that they agree to PHARMAC’s terms and conditions before the supplier’s Tender Bids are submitted.</p> <p><i>Refer to Appendix B: Screen flows</i></p> | Must | P&C | |
| FR-070 | The solution shall allow a supplier to edit and resubmit a Tender Bid . | Must | P&C | Suppliers should be warned that resubmitting their bid after the |

| ID | Description | Priority | Source | Comments |
|--------|--|----------|--------|--|
| | <p><i>Scenario:</i> if a supplier makes a mistake in their submitted Tender Bid/s whilst the tender is still open they can edit and resubmit their Tender Bid/s.</p> <p>Only the latest submitted Tender Bids will be provided to PHARMAC. recorded in the system.</p> | | | tender deadline but before the tender close time will result in all their bids being received after the tender close time. |
| FR-071 | <p>The solution should provide a function for a supplier to delete all data entered for a Tender Bid or a Tender Item. This action should require confirmation by the user to prevent accidental data loss.</p> <p>This function would not be available after the tender close time.</p> | Should | P&C | This would be similar to a “reset” function which would set all fields to blank. |

6.2.4 Close of tender Requirements

| ID | Description | Priority | Source | Comments |
|--------|--|----------|--------|---|
| FR-100 | <p>The tender must have two key dates and times related to the closing of the tender, which must be able to be set independently:</p> <ul style="list-style-type: none"> A published date and time that tender bids must be submitted by. This is displayed on the website as the tender close time. This will be known as the “tender deadline”. The close date and time, after which the tender system will not accept bids. This will be known as the “tender close time” which may not be published on the website. <p>The tender must automatically close at the “tender close time”.</p> | Must | P&C | Suppliers tend to leave things until the last minute and/or have technical issues during final submission. PHARMAC can consider and accept late bids at its discretion. |
| FR-101 | After the “tender deadline” the home screen of the solution shall display a message that the tender deadline has passed but that late Tender Bids can be considered and accepted at PHARMAC’s discretion. | Must | P&C | |
| FR-102 | After the “tender close time” the home screen of the solution shall display a message that the tender has closed. | Must | P&C | |
| FR-103 | The solution shall allow PHARMAC to export all Tender Bids and relevant tender information for import into PHARMAC internal systems. Export functions must not be available until after the “tender close time”. | Must | P&C | |

| ID | Description | Priority | Source | Comments |
|--------|--|----------|--------|--|
| | Details of the export format are to be decided, XML is preferred. | | | |
| FR-104 | <p>The solution must provide PHARMAC with the ability to reopen the tender; the system should notify all suppliers when a tender is reopened.</p> <p>Rationale: <i>Should an event occur that could impair suppliers ability to submit their Tender Bids this function would allow PHARMAC the opportunity to reopen the tender to allow suppliers to submit Tender Bids later than the original deadline.</i></p> | Must | P&C | |
| FR-105 | <p>The supplier must be able to create a downloadable list or report of Tender Bids submitted on a tender. This should include all information entered by the supplier, with attachment names listed rather than including the attachments. Tender Bids that are incomplete should be included, clearly marked as “incomplete, not submitted”. This information must be provided as a PDF file, and could additionally be provided as a CSV file.</p> <p>This report must be available while the tender is open and after it closes, for a period of time defined by PHARMAC.</p> <p>After a supplier submits their tender bids they must have the option to download this list or report.</p> | Must | P&C | <p>Suppliers need to have access to the bids they placed for their own records.</p> <p>There is some flexibility regarding the information produced in this requirement.</p> |

6.3 Non-Functional Requirements

6.3.1 General NFRs

| ID | Description | Priority | Source | Comments |
|---------|---|----------|--------------|----------|
| NFR-001 | The solution should conform to New Zealand Government Accessibility and Usability Standards (see link in resources section above). | Must | ICT Services | |
| NFR-002 | Solution provider must be able to provide user support but have no access to data. E.g. Support provided via screen sharing. | Must | P&C | |
| NFR-003 | The solution shall be accessible using a web browser over the public Internet. | Must | P&C | |

6.3.2 User Access/Security Requirements

| ID | Description | Priority | Source | Comments |
|---------|---|----------|--------------|---|
| SEC-001 | The data in the system is rated "In Confidence". See security classifications reference in Government Standards and Tools section above. | Must | ICT Services | https://protectivesecurity.govt.nz/home/information-security-management-protocol/new-zealand-government-security-classification-system/ |
| SEC-002 | Data is to be encrypted in transit. Use approved cryptographic algorithms and protocols as defined by NZISM. | Must | ICT Services | |
| SEC-003 | All servers or systems involved with storing and managing the tenders, tender bids, relevant tender information and supplier details must be secure, running up to date, supported software, including operating system. Software updates and patches should be applied regularly. | Must | ICT Services | |
| SEC-004 | A computer generated time-stamped audit trail shall be used to record the date and time of all user entries and actions that create, modify, delete, and view electronic records within the solution. Specific examples of audit log entries that are required include but are not | Must | ICT Services | |

| ID | Description | Priority | Source | Comments |
|---------|--|----------|--------------|----------|
| | <p>limited to:</p> <ul style="list-style-type: none"> • Entering or modifying any information in the system, particularly Tender Bids • User logins, modifying user or supplier information • Viewing Tender Bids (this may be used to prove neither PHARMAC or other suppliers viewed a Tender Bid) • Recording all notifications sent (in order to prove important notifications are sent to suppliers) • Submitting a Tender Bid • Reopening bidding <p>Audit logs must not be able to be modified. Audit log access must be recorded in the audit log.</p> <p>Rationale: PHARMAC has a requirement to retain specific data under the Official Information Act (OIA) 1982. This information can be used in court if PHARMAC is challenged.</p> | | | |
| SEC-005 | <p>Information entered by suppliers in response to the tenders must not be visible to anyone (i.e. other suppliers, PHARMAC staff, Entity operating the tenders) while the tender is open unless they are authorised by the supplier. After the tender closes PHARMAC staff can see all information for all suppliers.</p> <p>Rationale: Data in the solution is commercially sensitive and highly confidential; failure to meet this condition will have significant negative impacts on the outcome of the tenders and PHARMACs ability to fulfil its mandate for the New Zealand Government.</p> | Must | PHARMAC | |
| SEC-006 | <p>The solution shall lock accounts after 5 unsuccessful login attempts in 30 minutes. The account may not be logged into until PHARMAC or the solution provider manually unlocks the account.</p> | Must | ICT Services | |

| ID | Description | Priority | Source | Comments |
|---------|---|----------|--------------|----------|
| | The account could automatically unlock 24 hours after it is locked. | | | |
| SEC-007 | <p>Security and penetration testing of the solution will be undertaken on a regular basis by a qualified person/organisation either employed by the solution provider or nominated and approved subcontractor, no less than annually. A report on the results must be supplied to PHARMAC.</p> <p><i>Rationale: the solution provider should demonstrate a commitment to providing a secure platform.</i></p> | Must | ICT Services | |
| SEC-008 | <p>Attachments should be scanned for viruses and other malware.</p> <p>Only Word documents, excel spreadsheets, PDF files, picture file and text documents should be able to be uploaded (doc, docx, xls, xlsx, odf, rtf, pdf, txt, jpg, jpeg, gif, png extensions).</p> | Should | P&C | |
| SEC-009 | The solution shall not reveal any information about registered suppliers, users, or Tender Bids to anyone not explicitly authorised. I.e. there must be no way for anyone to determine if a given organisation or person is registered or associated with a given tender | Must | ICT Services | |

6.3.2.1 Roles and Access Control (Production Environment)

The following security user roles have been identified for this solution:

| Role | Responsibility | Permissions | Description or Comments |
|---|--|--|-------------------------|
| Developer | Development and customisation of the solution | No access to Tender Bids and relevant tender bid information in the production system. | |
| Administrator (solution provider/vendor) | Technical level administration of the solution | No access to Tender Bids and relevant tender bid information in the production system. Access to user information to provide support and reset passwords. | |
| PHARMAC Tender Administrator | Business level administration of the tender | No access to Tender Bids in the solution until after the tender has closed. This includes no access to the export function. User configuration of solution. Tender: Create, edit, delete tenders, add attachments, add suppliers, mark suppliers as approved or unapproved, set time frames and reminders/notifications. Maintain supplier and product list: Add, edit, remove suppliers (users and approvers) and products. | |

| Role | Responsibility | Permissions | Description or Comments |
|------------------------|--|--|---|
| Non-validated supplier | None | Open tenders are visible. No access to submit Tender Bids . | |
| Supplier User | Respond to the multi-product tender on behalf of the supplier | <p>Access Tender Bids where they are the supplier named.</p> <p>Tender: create, view, edit, save, delete and tender bids, add attachments.</p> <p>No permission to submit Tender Bids on behalf of the supplier named.</p> | |
| Supplier Approver | Same responsibilities as Supplier User, plus the ability to submit tender bids on behalf of the supplier | <p>All access and permissions as Supplier User.</p> <p>Permission to submit all Tender Bids on behalf of the supplier named.</p> | This user role is similar to an administrator for the organisation. |

6.3.2.2 Access Control Matrix

| | Developer (Solution provider/vendor) | Administrator (Solution provider/vendor) | PHARMAC Tender Administrator | Supplier User | Supplier Approver | Public / Anonymous / Unregistered |
|--|--|--|------------------------------------|------------------|----------------------|---|
| Create New Tender | | | X | | | |
| View Tender | X | X | X | X | X | X |
| View Registered Suppliers & Users | | X | X | | | |
| View Supplier and User Details | | X | X | | | |
| View / Edit Own Organisation Users, Details, Credentials | | X | X | | X | |
| Approve Supplier Registration | | | X | | | |
| Change Any User Password or information | | X | X | | | |
| Change own user information | | X | X | X | X | |
| Create PHARMAC User(s) | | X | X | | | |
| Create Supplier Users | | X | X | | X | |
| View Tender Bids (within supplier organisation) | | | | X | X | |
| Create Tender Bid (within supplier organisation) | | | | X | X | |
| Edit Tender Bid (within supplier organisation) | | | | X | X | |
| Submit supplier Tender Bids | | | | | X | |
| Re-open Bid for given supplier (to make correction / additional bid) | | | | | X | |
| Export Tender Bids for individual supplier (pdf / csv) | | | | X | X | |
| View all Tender Bids made by all suppliers | | | X Only after tender has closed | | | |
| Export all Tender Bids | | X Only after tender has closed | X Only after tender has closed | | | |
| Delete all Tender Bids and associated information from solution | | X | X | | | |

6.3.3 Performance and Scalability Requirements

| ID | Description | Priority | Source | Comments |
|--------|---|----------|--------------|----------|
| SL-001 | 90% of pages that do not modify data or system state should load within 3 seconds. | Must | ICT Services | |
| SL-002 | 98% of pages that do not modify data or system state should load within 5 seconds. | Must | ICT Services | |
| SL-003 | 90% of pages that modify data or system state should load within 3 seconds. Sending attachments to the system are except from this requirement, but should complete within a reasonable amount of time. | Must | ICT Services | |
| SL-004 | 98% of pages that modify data or system state should load within 6 seconds. Sending attachments to the system are except from this requirement, but should complete within a reasonable amount of time. | Must | ICT Services | |
| SL-005 | The system should initially be sized to support 300 logged in users entering tender bids, relevant tender information and submitting tender bids. The system should be capable of being sized to support 1000 logged in users. | Must | P&C | |

Note that performance measures should be done from inside New Zealand, as this is where 90% of users are located. Performance testing is to be done with the simulated load as specified in SL-005.

6.3.4 Support and Maintenance Requirements

| ID | Description | Priority | Source | Comments |
|--------|---|----------|--------------|----------|
| SM-001 | The RPO (recovery point objective) is 10 minutes for all information submitted to the system. | Must | ICT Services | |
| SM-002 | The RTO (recovery time objective) is 8 business hours between 8am and 5pm Monday to Friday (New Zealand time). Please note exceptions to this RTO are noted in section 6.3.7, Service Level Requirements. | Must | ICT Services | |
| SM-003 | Off-site backups must be kept in accordance with industry best practice. These backups should be daily, but must be at least weekly. | Must | ICT Services | |

6.3.5 Integration Summary

The following table lists likely integrations with other systems.

| ID | Target System | Description |
|----|-----------------------|--|
| 1 | PHARMAC Tender System | Export of tenders to PHARMAC's internal tender system after a tender is closed. Prefer XML format. |

6.3.6 Capacity and Availability Requirements

| ID | Description | Priority | Source | Comments |
|--------|---|----------|--------------|----------|
| CA-001 | The solution initially needs to be available to approximately 50-60 suppliers/300 users (international and domestic). The solution will be scalable up to 1,000 users. | Must | P&C | |
| CA-002 | The solution will be accessible to users using the following web browsers: <ul style="list-style-type: none">• Safari v6.0 and above on Mac OS-X• Google Chrome v27 and above on Mac OS-X, Windows and Linux (Ubuntu 14.04 LTS)• Windows Internet Explorer v8 and above on Windows• Firefox v22.0 and above on Windows and Linux (Ubuntu 14.04 LTS)• Microsoft Edge on Windows 10 (Edge version current as at testing date) | Must | ICT Services | |
| CA-003 | The system must be available 99.8% of the time. | Must | ICT Services | |
| CA-004 | System maintenance should not be performed during the final week of PHARMAC's current annual tender unless it is critical to keep the system operational and secure | Should | ICT Services | |

Note that browsers must be tested on Windows, Mac OS X and Linux versions that are currently under mainstream support. Specifically:

- [Windows 7, 8, 8.1, and 10](#)
- Mac OS X 10.7 and later (NB: Apple do not seem to publish support life cycles for OS-X)
- Ubuntu 14.04 LTS, 15.10. Linux is a lower priority than Windows/Mac and more consideration may be given.
- NB: Windows XP and Windows Vista are [no longer in mainstream support](#) (see <http://windows.microsoft.com/en-nz/windows/lifecycle>)
Compatibility is desirable but not required.

6.3.7 Service Level Requirements

PHARMAC requires levels of support that vary throughout the tender process. Currently only one tender is run per year, starting early November closing in mid-December, though this could potentially change in the future.

Note that PHARMAC acknowledge that resolution of complex issues may fall outside the following windows, but all reasonable efforts should be made to meet the specified times.

| Query Type | Query Timing | Required Response Time | Target Resolution Time | Comments |
|--------------------------|-------------------------------------|----------------------------------|---|----------|
| Tender or system related | Tender not running | 48 hours | System RTO | |
| Tender or system related | Tender being prepared | 24 hours | System RTO | |
| Tender or system related | Tender open | 24 hours | System RTO | |
| Tender or system related | Final three business days of tender | 2 hours | System RTO | |
| Tender or system related | Final day | 60 minutes | 60 minutes | |
| Security query | Any | 2 business days | | |
| Security problem report | Any | Initial response: 1 business day | Incident mitigation (where possible): 2 business days Incident target repair time: 5 business days | |

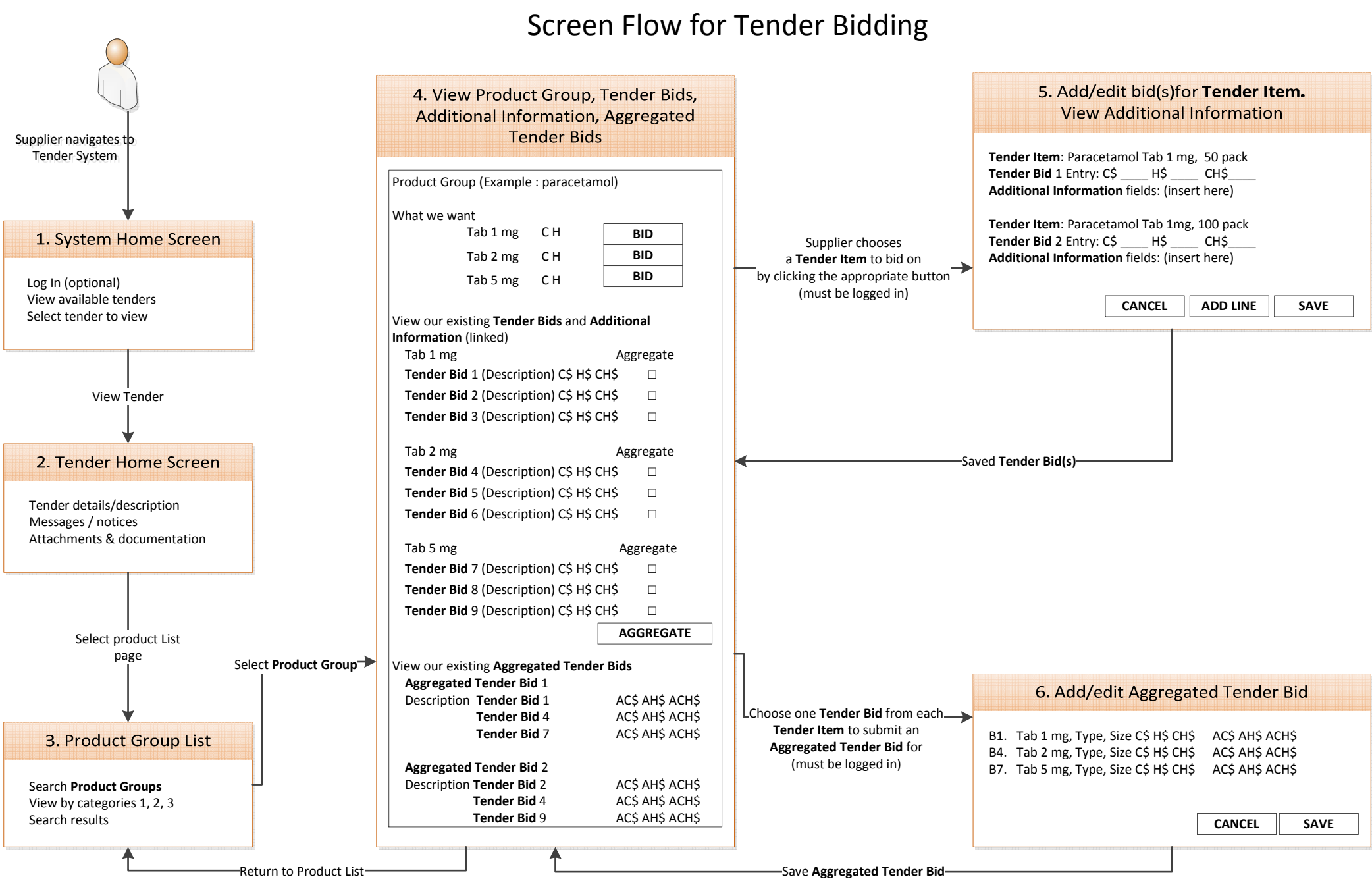
7 Appendix A: Glossary of Terms

| Term/Acronym | Definition/System/Application | Description |
|------------------------------|---|--|
| Aggregated Tender Bid | | Tender Bids for more than one Tender Item , which PHARMAC is to consider in aggregate, that includes Tender Bid prices for more than one Tender Item of the same Product Group but not aggregation within a single Tender Item . |
| Bid Submission | | The supplier confirms that a single Bid Submission of all completed supplier Tender Bids should be sent to PHARMAC when the tender closes. |
| DHB | District Health Board | |
| GETS | Government Electronic Tender Service | GETS is a free web-based service which allows you to view and respond to information on current New Zealand Government procurement opportunities. It is designed to promote open, fair competition in the New Zealand Government market and meet international trade agreement commitments to provide information about New Zealand Government business opportunities. |
| ISO | International Standards Organisation | |
| ITT | Invitation to Tender | |
| NZISM | New Zealand Information Security Manual | The New Zealand Information Security Manual presents baseline and minimum technical security standards, as well as providing technical, information assurance and security guidance for Government departments and agencies. |
| PHARMAC | Pharmaceutical Management Agency | |
| TGM | PHARMAC Therapeutic Group Managers | |
| Category | | All Tender Items are in a hierarchy of Categories |
| Product Group | | A Chemical Entity or a medical device product group of Tender Items . E.g. paracetamol |
| Solution Provider | | Organisation that provides the IT solution to run the external tender system |
| Supplier | | Pharmaceutical provider who may or may not bid in a PHARMAC tender |
| Tender Item | | A specified item that can be bid on in the |

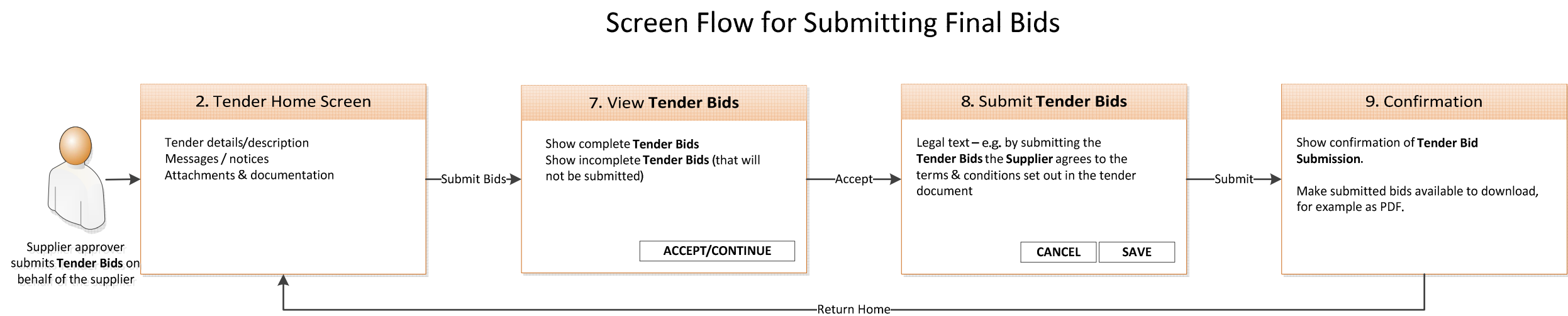
| | | |
|-------------------|--|---|
| | | tender. E.g. paracetamol, Tab 500 mg |
| Tender Bid | | A single Tender Bid for a Tender Item . e.g. a Tender Bid for Community supply of Paracetamol Tab 500 mg with “Brand X, Product Y, 1,000 Tab blister pack” at \$XX.XX |

8 Appendix B: Screen flow

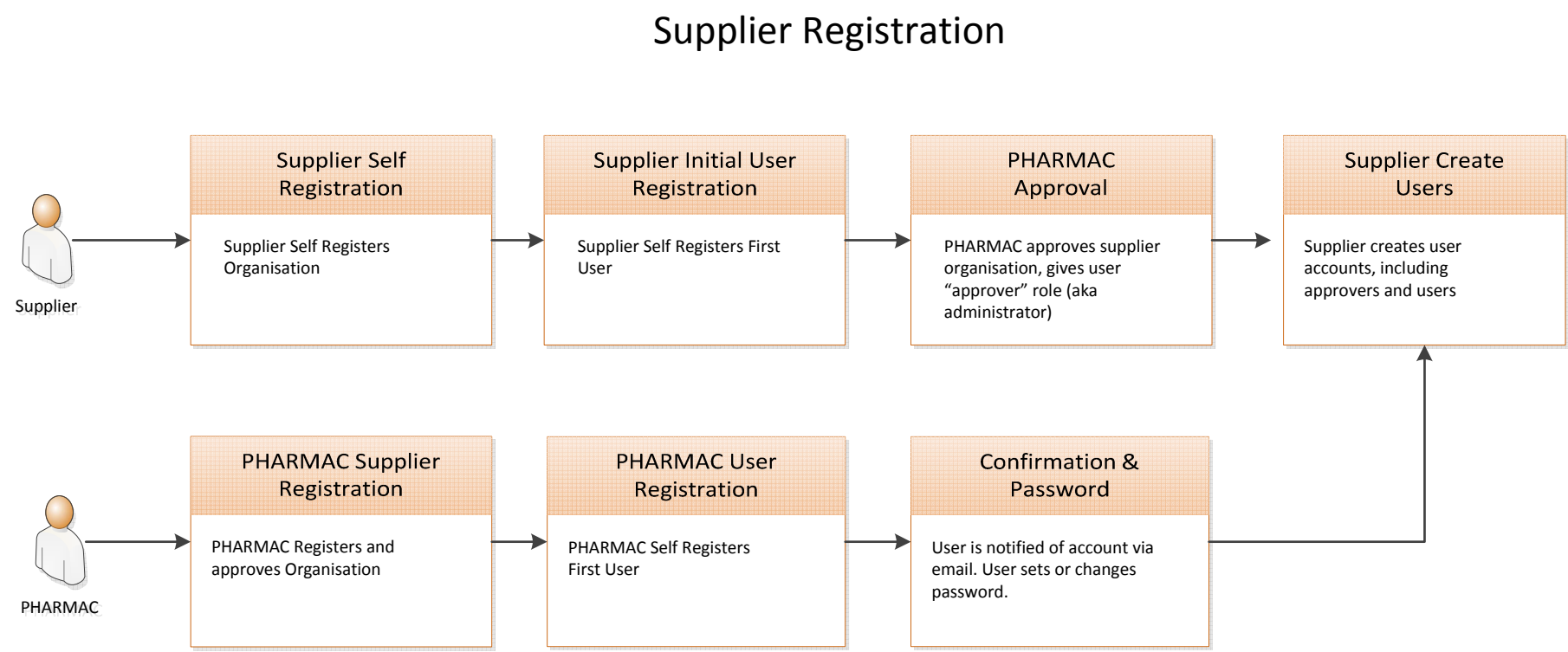
8.1 Screen Flow for Bidding



8.2 Screen Flow for Submitting Bids



8.3 Screen Flow for Supplier Registration



9 Appendix D: Notifications and Reminders

The following alerts should be possible. The text of the alerts is to be defined at a later date.

| Notification # | Condition/ Trigger | Sent to | When ⁹ |
|----------------|--|--|--|
| 1 | Tender is opened to suppliers for bids | All suppliers (users and approvers) | Immediately |
| 2 | Suppliers registered subsequent to the opening of the tender | Suppliers registering after tender opening – supplier (users and approvers) | Immediately |
| 3 | Seven days before closing date of tender | Suppliers who have not entered or submitted their bids – suppliers (users and approvers) | Seven days before the closing date of tender |
| 4 | 48 hours before close of tender | All suppliers associated with a tender (users and approvers) | 48 hours before close of tender |
| 5 | Tender Closed | All suppliers | Immediately |
| 6 | Tender entered and saved but not yet submitted | Supplier (users and approvers) | One week after tender bid is saved |
| 7 | Tender entered and saved but not yet submitted and 48 hours before close of tender | Supplier (users and approvers) | 48 hours before close of tender |
| 8 | When bids are submitted by approver/s | Supplier approvers | Immediately |
| 9 | Tender re-opened | All suppliers (users and approvers) | Immediately |

⁹ To be set by PHARMAC

10 Appendix E: Data fields

The information provided is indicative and is highly likely to be changed or refined before implementation.

10.1.1 Supplier Information

| Ref# | Name of Field | Type | Comments/ Condition | Mandatory Field |
|------|----------------------|---------------|------------------------|-----------------|
| 1 | Supplier ID | Long | | Y |
| 2 | Supplier Name | Free text | | Y |
| 3 | Address Lines 1 | Free text | | Y |
| 4-7 | Address Lines 2-5 | Free text | | N |
| 8 | City | Free text | | Y |
| 9 | Postcode or zip code | Free text | | N |
| 10 | Country | Free text | | Y |
| 11 | Contact Name | Free text | | Y |
| 12 | Contact Phone Number | Free text | | Y |
| 913 | Email Address | Email address | | Y |

10.1.2 Category 1 - 3

The following are primarily for grouping.

| Name of Field | Type | Mandatory Field |
|--------------------|---------|-----------------|
| Category ID | Integer | Y |
| Parent Category ID | Integer | Y |
| Category name | String | Y |

10.1.3 Product (Pharmaceutical)

The following are primarily for grouping or searching

| Name of Field | Type | Mandatory Field |
|--------------------|---------|-----------------|
| Product ID | Integer | Y |
| Parent Category ID | Integer | Y |
| Chemical name | String | Y |

10.1.4 Tender Item (Pharmaceutical)

The data fields in the following table will be populated by PHARMAC

| Name of Field | Type | Comments/ Condition | Mandatory Field | User Visible |
|------------------------------|----------|--|-----------------|--------------|
| Tender Item ID | Integer | Database identifier | Y | N |
| Formulation code | Integer | Link to PHARMAC internal system | Y | N |
| Line item ID | Integer | Link to PHARMAC internal system | Y | N |
| Product ID | Integer | Links to product name | Y | N |
| Tender Item Description | Text | Formulation – e.g. 500mg capsule, box of 50 | Y | Y |
| Units Supplied | Integer | Number of units supplied in previous financial year | Y | Y |
| Cost | Currency | NZD Expenditure in previous financial year, excludes confidential rebate if applicable | Y | Y |
| Current Unit Subsidy | Currency | As at the time of release of the tender ¹⁰ | Y | Y |
| Current Partial Subsidy Flag | Boolean | Whether the item is currently fully or partly funded | Y | Y |

¹⁰ Flexibility is required to include future hospital figures, and distinguish between the community and hospital figures.

| | | | | |
|------------------------------|------------|---|---|---|
| Current Patent flag | Boolean | Whether the product is thought to be under patent | Y | Y |
| ASP flag | Boolean | Additional Stock Pharmaceutical: for most products suppliers are required to hold two months of stock, but for ASP drugs suppliers are required to hold four months of stock. | Y | Y |
| Rebate | Boolean | Some items have rebates associated with them. Important to identify these as the “cost” section above does not include rebate. | Y | Y |
| Community Supply | Boolean | Whether PHARMAC wants community supply bids | Y | Y |
| Hospital Supply | Boolean | Whether PHARMAC wants hospital supply bids | Y | Y |
| Discretionary Variance Limit | Percentage | Hospitals typically have to use only the medications funded. There is an allowance to use other brands for reasons of medical necessity | Y | Y |
| Comments | Text | | N | Y |

10.1.5 Tender Bid (Pharmaceutical)

The data fields in the following table will be populated by the suppliers for each product line item.

| Name of Field | Type | Comments/ Condition | Mandatory Field | User Visible |
|------------------------------|---------------|---|----------------------------|--------------|
| Tender Item ID | Integer | The tender item this bid is associated with | Y | N |
| Community Pack Size | Free text | Size of the pack supplied to community pharmacies | Y | Y |
| Hospital Pack Size | Free text | Size of the pack supplied to hospital pharmacies | | |
| Unit Packaging | Drop down box | PHARMAC will add/amends these categories as required | Y | Y |
| Brand/Trade Name | Free text | E.g. Panadol is a brand name for paracetamol | Y | Y |
| Market Approval | Boolean | Whether approved for sale/use in NZ | Y | Y |
| NZD Community bid pack price | Currency | Bid for community supply | N One bid type required | Y |
| NZD Hospital bid pack price | Currency | Bid for hospital supply | N One bid type required | Y |
| NZD Combined Bid pack price | Currency | Bid for combined community and hospital supply. Both hospital and community bids required before this field can be entered. | N | Y |

10.1.6 Additional Information

| Name of Field | Type | Comments/ Condition | Mandatory Field | User Visible |
|-------------------------------------|-----------|--|---------------------|--------------|
| Parent ID | Number | May be linked to a product, a tender item, or both. Details TBC with system supplier. | | |
| Date of market approval | Date | | One of 2-4 required | |
| Date of submission of dossier | Date | | One of 2-4 required | |
| Expected date of dossier submission | Date | | One of 2-4 required | |
| Lead Time (days) | Integer | Lead time for supplier (on the basis of your assessment of the size of the market for the Tender item) Lead time must be recorded at the tender line level rather than at the chemical level. Definition for lead time will be outlined in the Invitation to Tender. | Y | |
| Lead Time Comments | Free text | | N | |
| Manufacturer Details | Free text | Name and location of manufacturer(s) of finished product | Y | |
| Packaging Site Details | Free text | Name and location of packaging site | Y | |

| Name of Field | Type | Comments/ Condition | Mandatory Field | User Visible |
|--|-----------|---|-----------------|--------------|
| Active Ingredient Manufacturer Details | Free text | Name and location of manufacturer(s) of active ingredients | Y | |
| Manufacturer Details Alternate | Free text | Alternative name and location of manufacturer(s) of finished product (if any) | N | |
| Active Ingredient Manufacturer Details Alternate | Free text | Alternative name and location of manufacturer(s) of active ingredients (if any) | N | |
| Distribution Details | Free text | Proposed supply and distribution for the Tender item | Y | |
| Pharmacode | | Medication identifier | N | |
| GTIN | | Medication identifier | N | |
| NZMT | | Medication identifier | | |
| Attachments | Files | Attachments upload as part of the tender bid by the supplier will be linked to the specific product item. | N | |

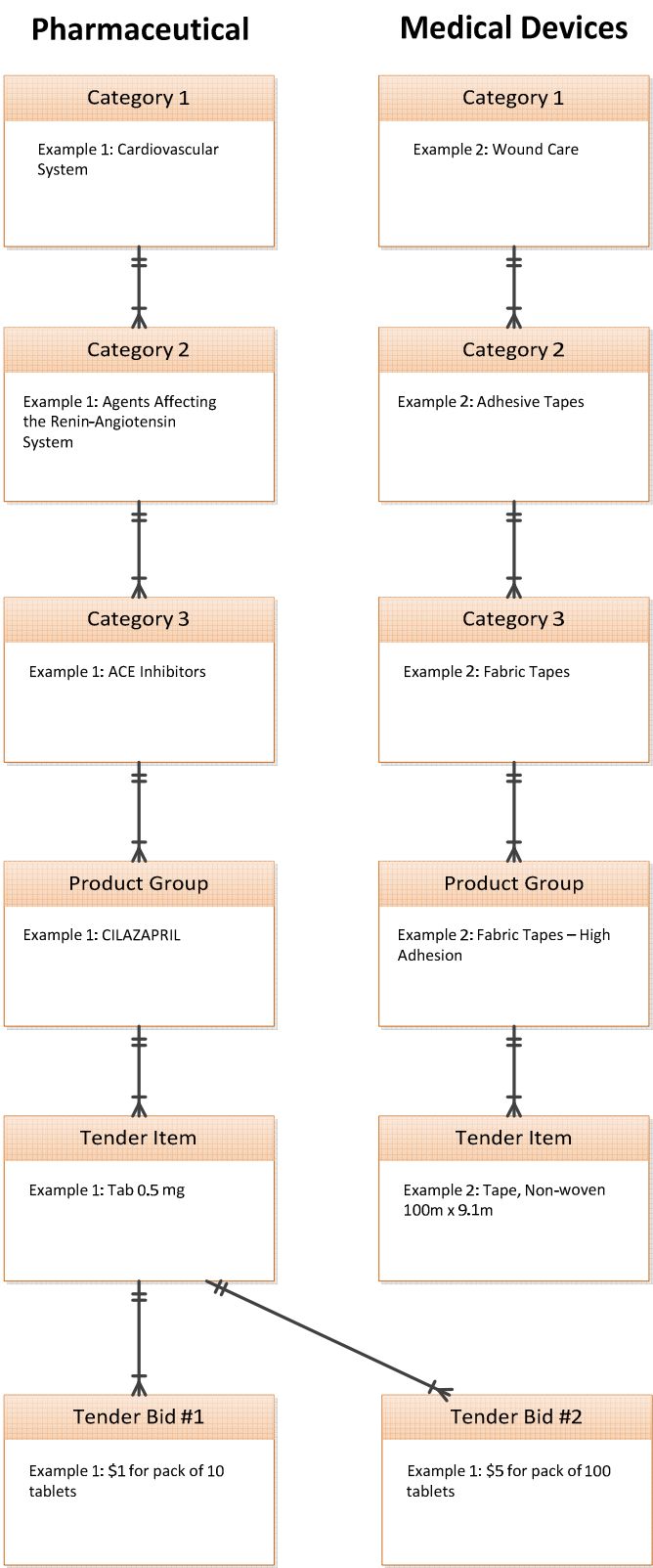
10.1.7 Tender Item (Medical Devices)

The following is an early draft meant to show that medical device tender items would be significantly different from pharmaceutical products.

| Name of Field | Type | Comments/ Condition | Mandatory Field | User Visible |
|------------------------|---------|------------------------|-----------------|--------------|
| Device ID | | | | N |
| Product ID | Integer | Links to product name | Y | N |
| Supplier ID | | | | N |
| Supplier Product Code | | | | Y |
| Brand Name ID | | | | N |
| Device Name ID | | | | N |
| Device Name | | | | Y |
| Supplier Name | | | | Y |
| UOMID | | | | Y |
| Pack size | | | | Y |
| Additional information | | | | Y |
| GTIN | | | | Y |

| | | | | |
|--------------------|--|--|--|---|
| UNSPSC | | | | Y |
| WAND | | | | Y |
| Original Device ID | | | | Y |

11 Appendix F: Data Model



12 Appendix G: User Structure

