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23 May 2024

Dear Supplier

**INVITATION FOR REGISTRATION OF INTEREST – SUPPLY OF PERSONAL PROTECTIVE EQUIPMENT ("INVITATION")**

Pharmac invites registrations of interests ("ROIs") to supply personal protective equipment (PPE) to Health New Zealand | Te Whatu Ora hospitals.

This Invitation is stage one of a procurement process. Stage two will advertise the opportunity to be selected for a panel of suppliers. A submitter who is notified by Pharmac that its ROI has been accepted is eligible to participate in the opportunity to be selected for a panel of suppliers for the PPE.

This Invitation incorporates the following schedules:

- Schedule 1 sets out the background, scope and description of ROIs sought;
- Schedule 2 describes the process that Pharmac expects to follow in relation to the Invitation; and
- Schedule 3 and Attachment 1 specifies the information a submitter needs to include in its ROI and contains the form in which a submitter is to provide the details of its ROI.

Health New Zealand currently and will continue to manage the national supply chain for PPE products and will likely undertake some discrete procurement processes to meet operational requirements while Pharmac establishes the panel of suppliers. Pharmac will be working closely with Health New Zealand as it establishes the new arrangements, and the new arrangements from Pharmac will supersede existing ones at the time they are implemented.

If a submitter wishes to submit a ROI in response to the Invitation, please submit it via the Government Electronic Tenders Service (**GETS**) no later than **5.00pm Thursday 20 June 2024.**

If a submitter has any questions about this Invitation, please post these on GETS by **5.00pm Thursday 6 June 2024**. Responses to all questions will be published on GETS.

We look forward to receiving your ROI.

Yours sincerely

Catherine Epps

Catherine Epps
Director, Medical Devices

## Schedule 1: Background, description of ROIs sought and scope for Personal Protective Equipment

### 1. Background to Invitation

In response to the COVID-19 pandemic, supply of PPE has been centrally managed at a national level. PPE will continue to be centrally managed for Health New Zealand hospitals but from 1 October 2023 the Manatū Hauora – Ministry of Health funded element has been discontinued and new arrangements need to be entered.

### 2. Description of ROIs Sought

Pharmac, in conjunction with Health New Zealand, is undertaking a multi-staged procurement process for establishing national listing agreements **(National Contracts),** from a panel of suppliers, for the supply of PPE to Health New Zealand hospitals.

The ROI will be assessed by Pharmac and as a result of that assessment each submitter will be notified whether its ROI has been accepted or not (see Schedule 2, paragraph 4). Pharmac intends to issue further procurement processes by sub-category at a later date, to advertise the opportunity to be selected for a panel of suppliers. Submitters must submit a ROI and the ROI must be accepted to be eligible to submit a response to any further procurement process.

Schedule 3 contains the ROI response form in which a submitter is to provide details of its submission.

Pricing proposals are **not** to be included with the ROI. Pricing would be sought as part of any further procurement process.

Please note the notice of procurement for any panel of suppliers will include but not be limited to the terms and conditions of supply that will apply, the method of awarding contracts and the period of time the panel will be established.

The number of suppliers awarded in each sub-category of PPE will vary depending on the product type but is anticipated to be between one and five. PPE that is awarded a National Contract will be listed in Section H of the Pharmaceutical Schedule.

### 3. Scope of PPE category

The scope of the PPE category is as follows:

(a) Non-sterile gloves

  (i) Accessories (dispensers)

  (ii) Cytotoxic gloves

  (iii) Latex (sterile, non-sterile)

  (iv) Nitrile (sterile, non-sterile, high risk, cuff first)

(b) Gowns and aprons

  (i) Aprons

(ii) Coveralls

(iii) Cytotoxic gowns

(iv) Isolation/protective gowns

(v) Lead gowns/aprons/collars

(vi) Multiple use surgical gowns

(vii) Non-sterile surgical gowns

(viii) Procedure gowns

(ix) Surgical hood/helmet with surgical gown

(c) Disinfectant wipes and tablets

(d) Masks

(i) Procedure masks

(ii) Respirator masks

(iii) Surgical masks (tie, ear loop, laser, anti-fog, splash proof, visor, clear)

(e) Eyewear

(i) Face shields/visors

(ii) Goggles

(iii) Laser eyewear

(iv) Safety glasses

(f) Headwear

(i) Caps (tie back, elasticated, crimped, bouffant)

(ii) Hairnets

(iii) Surgeon hoods

(g) Other coverings

(i) Arm protectors

(ii) Beard covers

(iii) Boot covers

(iv) Chemical resistant overshoes/boots

(v) Ear muffs

(vi) Ear plugs

(vii) Shoe covers

(viii) Sleeve protectors

Pharmac anticipates releasing the stage two procurement processes in the order stated above though some sub-categories may be combined into a single process.

## Schedule 2: Invitation process

Pharmac expects to follow the process set out below in the sequence indicated.

1. **Submission**

(a) All ROIs must be submitted by a single submitter. Submitters may have joint commercial arrangements with other suppliers, and these can be combined into a single response.

(b) All ROI responses must be submitted to Pharmac via GETS no later than **5.00pm** (New Zealand time) on **Thursday 20 June 2024**. Late responses will only be considered at Pharmac's discretion, considering the need for fairness to other submitters and integrity of the Invitation process.

(c) A submitter cannot withdraw its ROI, once submitted, while the ROI process is continuing.

2. **Evaluation**

(a) Following the deadline for submitting ROIs an Evaluation Committee comprising of Pharmac and Health New Zealand staff will evaluate each ROI to determine which ROIs will be accepted in order to be eligible to participate in a further procurement process.

(b) The Evaluation Committee will evaluate ROIs in light of Pharmac's statutory objective, which is "to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided". In doing so, the Evaluation Committee will be guided by the Factors for Consideration (**FFC**) that form part of Pharmac's current Operating Policies and Procedures, as published on Pharmac's website, to the extent applicable. Please be aware of the FFC.

(c) The information considered during the evaluation process will be at the discretion of the Evaluation Committee however it will include:

(i) information and evidence provided by the submitter in accordance with Schedule 3 of this Invitation;

(ii) information that demonstrates the submitter's experience and ability supplying medical devices to Health New Zealand hospitals and other markets;

(iii) information about the submitter's company including but not limited to:

(A) evidence of financial stability and ability to cover financial liabilities;

(B) quality management systems;

(C) processes for complaints and recalls;

(iv) information about the submitter's ability to manage and support PPE, for example;

(A) product support;

(B) key supply continuity risks and mitigations;

(C) management of response to unexpected increases in demand;

(v) broader outcomes;

(vi) environmental sustainability;

(vii) labour and human rights;

(viii) Pharmac and Health New Zealand supplier experience;

(ix) any advice received from relevant clinicians and/or Health New Zealand hospital staff; and

(x) any other matters that the Evaluation Committee considers to be relevant (provided that Pharmac will notify such matters and allow an opportunity for submitters of ROIs to address them).

(d) ROI responses that do not demonstrate that they meet the requirement stated in paragraph (c)(ii) above will not be evaluated in their entirety and will not be eligible to participate in a further procurement process to be selected for a panel of suppliers.

(e) ROIs must meet all the mandatory information and evidence requirements as set out in Schedule 3.

3. **Pharmac may request further information**

(a) Pharmac may request such further information as it considers necessary from or about a submitter for the purposes of clarifying or evaluating the ROI, including (but not limited to) detailed information about a submitter's company structure, credit status and any other relevant company information.

(b) If Pharmac requests further information from or about a submitter, it is not obliged to request the same or any other information from or about any other party provided that, in Pharmac's judgment, this would not be unfair to any other party.

4. **Stage two of the Procurement Process**

In the event a ROI is evaluated and accepted, the submitter is eligible to submit a proposal in response to any future procurement process, for a panel of suppliers**,** which is issued by Pharmac for the PPE stated in Schedule 1. For the avoidance of doubt, it is at Pharmac's discretion as to whether a future procurement process is issued and it makes no representation in this respect.

5. **ROI Process Completion**

(a) The ROI process will be complete once Pharmac has notified:

(i) submitters whose ROI has:

(A) been accepted that they are eligible to submit a proposal in response to any future procurement process, for a panel of suppliers, for the PPE stated in Schedule 1; and

(B) not been accepted and are not eligible to submit a proposal in response to any future procurement process, for a panel of suppliers, for the PPE stated in Schedule 1; or

(ii) the termination of the Invitation process.

6. **Miscellaneous**

(a) Pharmac reserves the right, having regard to probity principles:

(i) to make such adjustments to the above Invitation process as it considers appropriate, at any time during the process, provided that it notifies submitters affected by those changes;

(ii) not to accept any ROI;

(iii) to seek clarification of any ROI;

(iv) to meet with any submitter in relation to its ROI;

(v) to suspend this Invitation process. For example, if during the Invitation process it becomes apparent to Pharmac that further consultation is appropriate or required we may suspend the Invitation process in order to consult. In this situation we may ask a submitter to adapt and resubmit its ROI in light of consultation, or alternatively we may request that a new ROI be submitted;

(vi) to terminate this Invitation process at any time, by notifying submitters who submitted ROI responses; and

(vii) to re-advertise for ROIs.

(b) The submitter must not initiate or engage in any communication with other submitters in relation to the Invitation, whether before or after submitting their ROI.

(c) The submitter must not at any time initiate any communication with Pharmac, Manatū Hauora (including its operation unit Medsafe), the Minister of Health (or any Associate Ministers) or Health New Zealand, or advisors to Pharmac, with a view to influencing the outcome of this Invitation process.

(d) The submitter must pay its own costs for preparing and submitting its ROI.

(e) The submitter must limit the information provided to that which is requested in Schedule 3 and provide it succinctly and clearly. Please do not provide brochures or additional information (eg PEHNZ forms and presentations) unless specifically requested to do so in this Invitation document.

(f) ROIs are submitted in reliance on the submitters own knowledge, skill, and independent advice, and not in reliance on any representations made by Pharmac.

(g) The submission of a ROI will be taken as acceptance of the terms contained in this Invitation. Pharmac may exclude the submitter's ROI if it does not comply with any of the terms contained in this Invitation document.

(h) This is an Invitation for ROIs and not a tender. The Invitation is not an offer capable of being converted into a contract for the supply of PPE by Pharmac's apparent acceptance. Any National Contracts for PPE would be with suppliers who were progressed to contract negotiation following ay future procurement process.

(i) Pharmac is not liable in any way whatsoever for any direct or indirect loss (including loss of profit), damage or cost of any kind incurred by a submitter or any other person in relation to this Invitation.

(j) Pharmac will consider the Invitation process and information exchanged between the parties relating to a submitters' ROI, excluding information already in the public domain, to be confidential to us and our employees, legal advisors and other consultants, Manatū Hauora and Health New Zealand ("**Confidential Information"**). However, the submitter acknowledges that it may be necessary or appropriate for Pharmac to release Confidential Information:

(i) pursuant to the Official Information Act 1982; or

(ii) otherwise pursuant to Pharmac's public law or any other legal obligations.

Pharmac may consult with the submitter before deciding whether to disclose Confidential Information for the purposes described in sub-clauses (i) to (ii) above. The submitter acknowledges, however, that it is for Pharmac to decide, in its absolute discretion, whether it is necessary or appropriate to disclose information for any of the above purposes, provided that Pharmac shall act in good faith in disclosing any Confidential Information.

## 7. Anticipated timetable

(a) Following receipt of ROIs, Pharmac anticipates:

(i) the Evaluation Committee evaluating ROIs from June 2024;

(ii) notifying submitters on the outcome of the Invitation in August 2024; and

(iii) releasing any future procurement process from September 2024 onwards.

provided that the above time frames are only approximate and may be extended, without notice being required from Pharmac, if any stages of the Invitation process take longer than anticipated.

## 8. Governing Law

This Invitation is governed by New Zealand law, and the New Zealand courts have exclusive jurisdiction in all matters relating to this Invitation.

## Schedule 3: Response form

An electronic version of this form is available on Pharmac's website and on GETS. You should expand the boxes as necessary.

**[*Supplier to insert date*]**

Director of Medical Devices
Pharmac
c/- Mikka Nocete
Device Category Manager

By electronic transfer using GETS

Dear Madam

**Registration of interest for the supply of personal protective equipment**

In response to your registration of interest (**ROI**) dated 23 May 2024 we put forward the following response in respect of supply of personal protective equipment (PPE) to Health New Zealand hospitals.

***You must also include information as outlined in Attachment 1 as part of your proposal.***

Set out below is further information in support of our response.

| **(a) Company details** | |
|---|---|
| Full legal trading name in New Zealand | |
| New Zealand Business Number | |
| Address | |
| Phone | |
| Email | |
| Facsimile | |
| **(b) Contact person(s) for this ROI** | |
| Name, Position | |
| Phone | |
| Mobile | |
| Email | |
| **(c) Any conflicts of interest** | |
| | |

| **(d) Information about our company** | |
|---|---|
| Type of entity (legal status)<br><br>Eg a New Zealand registered limited liability company | ***NB*** *Not required if you currently have a Pharmac agreement for supply of medical devices unless there have been changes to your business since the agreement was entered into.* |
| City and country of residence of our company | ***NB*** *Not required if you currently have a Pharmac agreement for supply of medical devices unless there have been changes to your business since the agreement was entered into.* |
| Information about company size, structure, and annual turnover<br><br>Include sales/product support staff relevant to PPE.<br><br>**Attach** Organisational Chart. | ***NB*** *Not required if you currently have a Pharmac agreement for supply of medical devices unless there have been changes to your business since the agreement was entered into.* |
| Total number of New Zealand based staff<br><br>Include FTE for each section (eg 5 FTE sale/product support, 4 FTE logistics, 3 FTE corporate and administration) | ***NB*** *Not required if you currently have a Pharmac agreement for supply of medical devices unless there have been changes to your business since the agreement was entered into.* |
| Established locations within New Zealand<br><br>Include function of each location (eg head office, warehouse). | ***NB*** *Not required if you currently have a Pharmac agreement for supply of medical devices unless there have been changes to your business since the agreement was entered into.* |
| Company ownership<br><br>State ownership (eg public ownership)<br><br>Include:<br>• any parent companies and relationships<br>• names and percentage shareholdings of the major shareholders and directors | ***NB*** *Not required if you currently have a Pharmac agreement for supply of medical devices unless there have been changes to your business since the agreement was entered into.* |
| Evidence of financial stability and ability to cover financial liabilities<br><br>Include:<br>• how you would cover your financial liabilities in the event of a major | ***NB*** *Not required if you currently have a Pharmac agreement for supply of medical devices unless there have been changes to your business since the agreement was entered into.* |

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| failure to supply (eg a recall)<br>• information about your financial stability (eg annual turnover, guarantor companies)<br><br>**Attach** supporting evidence (eg annual financial report, Companies Register financial statement, insurance certificate, bank letter). | |
| Does your organisation identify as being a Māori business?<br><br>Pharmac is committed to the Government's progressive procurement approach to increase the diversity of government suppliers and achieve broader economic and social outcomes, with a specific focus on Māori businesses. As part of this approach, Pharmac is committed to gaining a better understanding of how our agency can support the economic and social outcomes for Māori through our procurement.<br><br>Pharmac is therefore gathering information from organisations as to whether they identify as a Māori business.<br>A Māori business for Government procurement purposes is:<br>• One that has at least 50% Māori ownership, or<br>• A Māori Authority as defined by Inland Revenue.<br><br>Within these definitions, does your organisation identify as a Māori business? This information will inform Pharmac's supplier's database and will be reported to NZGPP, subject to any concerns you identify (see box below). | *[Yes / No]*<br><br>*In line with this policy, Pharmac is committed to understand and support what roles Māori businesses play in our supply chain. You can add any further comment on how your company supports economic and social outcomes for Māori below.* |
| For some of its procurement Pharmac is required to report to NZGPP on whether an organisation identifies as a Māori business as part of new progressive procurement reporting requirements.<br><br>Please indicate either 'Yes' or 'No' as to whether you agree to Pharmac reporting on your organisation's status as a Māori business. If you indicate 'No', clarification on why you do not wish to report on this would be appreciated. | *[Yes / No]* |
| New Zealand Government Broader Outcomes<br><br>Provide detail on how your Organisation supports social, economic, cultural and environmental outcomes beyond supply of Pharmaceuticals (see New Zealand Government Procurement Broader Outcomes).<br><br>Provide detail on how your organisation:<br>• supports New Zealand businesses, including Māori, Pasifika and regional businesses, as well as social enterprises if relevant | |

| | |
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| • supports improving conditions for New Zealand workers and support workforce diversity. | |

| **(e) Information about our experience supplying healthcare markets** | |
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| Experience supplying PPE to Health New Zealand hospitals<br><br>Provide detail on the experience that you have suppling PPE to Health New Zealand hospitals (and their DHB predecessor).<br><br>Include:<br>• any contracts that you have or previously had<br>• which hospitals you supplied<br>• how you ensured you understood the hospitals needs and that they were met<br>• as part of business-as-usual activity and during the COVID-19 pandemic | |
| Experience supplying medical devices other than PPE to Health New Zealand hospitals<br><br>Provide detail on the experience that you have suppling medical devices other than PPE to Health New Zealand hospitals (and their DHB predecessor).<br><br>Include:<br>• any contracts that you have or previously had<br>• which hospitals you supplied<br>• how you ensured you understood the hospitals needs and that they were met<br>• as part of business-as-usual activity and during the COVID-19 pandemic | |
| Experience supplying PPE to non-Health New Zealand hospital customers<br><br>Provide detail on the experience that you have suppling PPE to non-Health New Zealand hospitals.<br><br>Include:<br>• any contracts that you have | |

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| • which hospitals you supplied, including country<br>• how you ensured you understood the hospitals needs and that they were met<br>• as part of business-as-usual activity and during the COVID-19 pandemic | |
| Working with key stakeholders<br><br>Include information about how you envisage working with Pharmac and Health New Zealand key stakeholders. | |

| **(f) Information about our ability to manage and support PPE** | |
|---|---|
| Customer support hours<br><br>Include:<br>• standard support hours (NZ time) for customer support and orders<br>• any 24/7 troubleshooting support relevant to the proposed products | |
| Product support staff<br><br>Include information about technical skills, experience and qualifications of the staff that would be involved in supporting the proposed products (including those providing training and education). | |
| Complaints management processes<br><br>Include overview of key roles and responsibilities for investigation and response, and escalation and continuous quality improvement processes. | ***NB*** *Not required if you currently have a Pharmac agreement for supply of medical devices, the complaints process is uniform across all devices and there have not been changes to your business since the agreement was entered into.* |

| **(g) Quality Management System(s)** |
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| | | | |
|---|---|---|---|
| Does your company have a QMS? | *[Yes / No]* | | |
| Is your company ISO certified?<br><br>**If Yes, <u>attach</u> evidence**<br><br>Include relevant section(s) of standard where certification is not for full standard. | ISO 9001<br>*[Yes / No]* | ISO 13485<br>*[Yes / No]* | Other<br>*[Yes / No]* |
| Compliance with ISO standards<br><br>If your company is not ISO certified does it comply with ISO 9001 or ISO 13485? Please specify which standard your company complies with.<br><br>If your company does not comply with ISO 9001 or ISO 13485 please detail to what extent that it does comply. | *[Yes/No]* | | |

| **(h) Potential supply issues and response to unexpected increase in demand** | |
|---|---|
| Key supply continuity risks and mitigations<br><br>For each PPE range that you supply include the key risks to continuity of supply to Health New Zealand hospitals and the steps that will be taken to mitigate these risks. | |
| Response to unexpected increase in demand<br><br>In the event that you were to incur an unexpected increase in demand for PPE, either by Health New Zealand hospitals or other customers, detail how you would manage the increase in demand.<br><br>Include:<br>• any access to alternative international supply and timeframes<br>• communication with Health New Zealand hospitals | |

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| • communication with Pharmac<br>• how stock is prioritised<br>• other relevant information | |

| **(i) Environmental Sustainability** | |
|---|---|
| Does your Organisation have an environmental/sustainability policy?<br>If yes, attach or provide link. | Yes/No |
| Does your Organisation have a sustainability report?<br>If yes, attach or provide link. | Yes/No |
| How does your Organisation contribute to environmental sustainability?<br>Please describe the measures you take to contribute to environmental sustainability – in general and specifically in relation to this RFP. | |
| Has your Organisation received any environmental/sustainability award(s)?<br>If yes, provide details. | Yes/No |
| Has your Organisation received any environmental fine/prosecution(s)?<br>If yes, provide details. | Yes/No |
| Has your Organisation received any environmental audit(s) or does it comply with a recognised standard?<br>If yes, provide details. | Yes/No |
| Please provide detail on the sustainability initiatives that your Organisation has in relation to PPE.<br>This should include disposal of PPE following use, management of expired | |

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| product and any other alternative approaches that your Organisation has in place. | |

| **(j) Labour and Human Rights** | |
|---|---|
| Visibility over our supply chain?<br><br>Please select one of the below options and explain why you have selected this option:<br><br>**High:** we have mapped the full supply chain for key products and services used by our organisation and have identified key suppliers at all levels of your supply chain.<br><br>**Moderate**: we have identified major suppliers and have partially or fully mapped the supply chains for key products and services of our supply chain.<br><br>**Developing**: we have identified major suppliers. We have very limited or no visibility of our supply chains for key products and services of our supply chain.<br><br>**Other**: summary of the current status of our supply chain visibility<br><br>Please provide this for each stage of the supply chain:<br>• Distributor<br>• Factory of manufacture<br>• Refinement of raw materials<br>• Plantations where resins are cultivated | |
| Our organisation has a policy or policies in place to deal with modern slavery and worker exploitation | Yes/No |
| Our organisation has systems to monitor compliance with these policies? | Yes/No |

| | |
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| If you said yes to either of the two above questions, please attach or link.<br><br>If the answer is no, please provide information on what your organisation is doing, or plans to do, to manage modern slavery and worker exploitation risk. | |
| Our organisation performs continuous monitoring of all suppliers within the supply chain<br><br>If yes, please describe how your organisation performs its continuous monitoring for modern slavery and worker exploitation concerns, including what evidence can be provided.<br><br>If no, , please provide information on what your organisation is doing, or plans to do, to continually monitor modern slavery and worker exploitation risk. | Yes/No |
| Our organisation performs due diligence screening of all prospective suppliers to assess the risk of modern slavery or other human rights harms that may occur in its operations and supply chains<br><br>If yes, please describe how your organisation performs its due diligence for modern slavery and worker exploitation concerns.<br><br>If no, does your organisation plan to introduce measures to screen prospective suppliers from modern slavery and worker exploitation in future? | Yes/No |
| Our organisation complies with recognised standards<br><br>If yes, please identify the standard and outline the degree to which your organisation complies. | Yes/No |