# Schedule 4: Proposal form

An electronic version of this form is available on PHARMAC’s website at [www.pharmac.govt.nz](http://www.pharmac.govt.nz) and on GETS ([www.gets.govt.nz](http://www.gets.govt.nz)). You should expand the boxes as necessary.

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

Director of Operations  
PHARMAC

c/- Maree Hodgson

Senior Device Category Manager

By electronic transfer using GETS **(**[**www.gets.govt.nz**](http://www.gets.govt.nz)**)**

Dear Sir/Madam

**Proposal for the supply of non-invasive ventilation equipment, oxygen concentrators, respiratory gas humidifiers and associated products**

In response to your request for proposals (**RFP**) dated 30 April 2018 we put forward the following proposal in respect of non-invasive ventilation equipment, oxygen concentrators, respiratory gas humidifiers and associated products **(“NIV Products”)**

***Please refer to Schedule 3 for information and evidence to be included in your proposal. You must also include information as outlined Attachments 1, 3 and 4 as part of your proposal.***

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

1. Our contact details:

|  |  |
| --- | --- |
| Full legal trading name in NZ |  |
| Key Contact person |  |
| Address |  |
| Phone |  |
| Mobile phone |  |
| Facsimile |  |
| Email address |  |

1. Key features of our proposal and associated services available:

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1. Information relating to pricing ($NZ, GST exclusive) inserted in Attachment 1, including any related conditions or proposed terms:

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1. Information about the biocompatibility of our proposed skin contact products, in addition to the latex status as set out in Appendix 1:

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| --- |
| *[Including information about any reported adverse events relating to biocompatibility/allergies/sensitivities]* |

1. Information relating to NIV equipment included in proposal, in addition to that set out in Appendix 1:

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| --- |
| *[[Delivery lead in time]*  *[Product support, training and education]*  *[Other relevant information]* |

1. Information by DHB about NIV equipment supply arrangements to DHB Hospitals

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| *[Supply models offered currently]*  *[reason for continuing or not continuing to offer these models in the proposal]* |

1. Additional information relating to current NIV equipment supply options, including but not limited to outright purchase, lease, rent and rent to buy arrangements:

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| --- |
| *[Any differences between current arrangements with DHB Hospitals and proposed arrangements]*  *[if fleet options offered:*   * *Limitations and/or consumable requirements per device and or per DHB Hospital* * *Contingencies for peaks in demand* * *Assumptions used to estimate fleet size requirements* * *Delivery and retrieval timeframe(s)* * *Delivery, receipt and pre-use procedures* * *Management and operational arrangements including equipment tracking* * *Respective supplier and DHB responsibilities for fleet management* * *Risk and liability during key exchange and activity points]*   *[Product support, training and education]*  *[Termination terms and conditions]*  *[Other relevant information about the arrangement(s) being proposed]* |

1. Information about current contracts we have in place with DHB Hospitals, in addition to that included in Appendix 1:

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| --- |
| *[Expiry dates]*  *[Additional cost and volume data/information]*  *[Other relevant information about current contracts in place with DHB Hospitals]*  *[NIV Products or procurement options currently provided to DHB Hospitals that are* ***not*** *included in proposal, and reason for this]* |

1. Financial analysis of our proposal:

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| *[Overview of how proposed pricing compares to that currently offered to DHB Hospitals and total National cost impact of your proposal]*  *[****Attach*** *detail in Excel format as requested in schedule 3]* |

1. Information about our proposed distribution and supply arrangements including our ability to ensure continuity of supply to DHB Hospitals:

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| --- |
| *[Whether you are a manufacturer or distributor of the proposed NIV Products]*  *[Terms of any distribution agreements, if you are not the manufacturer, for example the duration and exclusivity of the distribution agreement]*  *[Description of supply chain used to bring stock to NZ]*  *[Details of distribution and stock-holding for New Zealand – including but not limited to amount of stock held and warehouse/distribution centre location(s) where it is held]*  *[Delivery frequency and lead in times, including under stable demand situations, in the event of supply disruptions, and when there is an unexpected surge in demand]*  *[Specific measures to secure stock for New Zealand from international production, including information about agreements in place with other parties in supply chain and notice periods required for any changes]*  *[Information relating to the manufacturing sites used to produce the products you propose, including but not limited to country of origin, whether one site has end to end production or if products are sent to other sites for finishing e.g. packaging, sterilisation etc]*  *[Any freight and delivery costs to DHB Hospitals – noting a preference for Free into Store arrangements]*  *[Other relevant supply chain arrangements]* |

1. Information about our other major markets and previous supply performance:

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| --- |
| *[Private New Zealand market(s)]*  *[International markets]*  *[Recent tenders awarded]*  *[Reference sites where proposed products are used in similar ways and settings to DHBs, and sales volumes for 1 Apr 2017 – 31 Mar 2018]*  *[Contact details for one clinical, one procurement and one technical (eg. clinical engineer) referee for non-NZ DHB sites]* |

1. Information about our organisation:

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| *[Organisational structure in NZ and globally (if applicable)]*  *[information about your ability to manage liability in the event of a major product recall or failure to supply event as described in Part 6 of PHARMAC’s standard terms and conditions for the supply of medical devices – refer to Attachment 2]*  *[Management, technical skills, experience and qualifications of staff in relation to the proposed NIV Products]*  *[Customer support hours for repairs, troubleshooting and advice]*  *[Other relevant information about organisation]*  *[Where any of the requested information has been provided to PHARMAC within the last twelve months in response to a previous Request for Proposal, provide the name and date of the RFP and detail any changes]* |

1. Information about our compliance with safety and performance standards:

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| --- | --- | --- |
| Standard | Information about the extent to which we conform with the standard | Conformance evidence **attached**? |
| AS/NZS IEC 60601-1: 2015 Medical electrical equipment – General requirements for basic safety and essential performance | *[include reference to relevant NIV Product(s)]* | *[Yes/No/NA]* |
| AS/NZS 3200.1.1:1995 Approval and test specification – Medical electrical equipment – General requirements for safety – Collateral Standard – Safety requirements for medical electrical systems | *[include reference to relevant NIV Product(s)]* | *[Yes/No/NA]* |
| AS/NZS 3200.1.2:2015 Medical electrical equipment – Part 1.2: General requirements for safety – Collateral Standard: Electromagnetic compatibility – Requirements and tests | *[include reference to relevant NIV Product(s)]* | *[Yes/No/NA]* |
| AS/NZS 3551:2012 Management programs for medical equipment | *[include reference to relevant NIV Product(s)]* | *[Yes/No/NA]* |
| AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organizations | *[include reference to relevant NIV Product(s)]* | *[Yes/No/NA]* |
| IEC standards and/or other relevant standards  *[Specify standard]* | *[include reference to relevant NIV Product(s)]* | *[Yes/No/NA]* |

1. Information about our Quality Management Systems

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| *[Information about conformance to ISO 900 Quality management or ISO 1345:2016 Medical devices quality management systems.* ***Attach*** *evidence where available]*  *[Information about our current or proposed complaints management processes, including ability to recall stock, refund or credit for damaged or faulty goods]*  *[Information about our business continuity planning in the event of an unexpected impact on our ability to supply our products, eg IT failure, manufacturing plant or product QC failure, force majeure event]* |

1. Our understanding of DHB educational requirements and our experience in providing training and product support for the NIV Products submitted:

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| --- |
| Clinical staff and technical personnel |

1. Information about our ability to support DHB transition to our NIV Products:

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| *[Overview of transition support with detailed transition plan* ***attached****]* |

1. Information about operating manuals, instructions and guides that would be provided for the safe and appropriate use, and maintenance, of our NIV Products

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| *[Overview of content of operating manuals, instructions and guides for the range of NIV Products proposed for clinical and technical personnel. Please* ***do not*** *include copies of full equipment operating or service manuals]* |

1. Information about our instructions and/or educational resources for patients

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| *[Overview of patient information resources for NIV Products intended for use in home settings]* |

1. Information about our current (and/or proposed) consignment stock management system:

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| *[Risk and liability arrangements]*  *[Responsibility for stock management including storage requirements, stock-takes, replenishment, discrepancy resolution]*  *[Auditing arrangements]*  *[Other relevant consignment stock management information]*  *[Provide detail in* ***Attachment 1*** *of which products a consignment model would apply to]* |

1. Details of our warranties and services for maintenance, servicing and calibration for reusable equipment:

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| --- |
| *[NIV equipment life expectancy and expected product upgrade cycle]*  *[Warranty information in addition to that included in Attachment 1, including warranties for repairs and spare parts]*  *[Frequency of calibration and maintenance]*  *[Performed by DHB clinical engineers on-site, or off-site service centre]*  *[Replacement and repair policies]*  *[Duration of availability of spare parts after date of delivery]*  *[Duration of availability of maintenance, servicing and calibration services after date of delivery]*  *[Cost of respective services including within the warranty period and following expiry of the warranty period]*  *[Training of DHB staff (eg. clinical engineers)]*  *[Other relevant information about maintenance, servicing and calibration services]* |

1. Information about equipment cleaning reprocessing:

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| *[Cleaning requirements during same patient use, including any specialised cleaning equipment and products]*  *[Reprocessing requirements between patients, including any specialised reprocessing equipment and products]*  *[Other relevant information about cleaning and reprocessing]* |

1. Information about manufacturing waste reduction policies and within New Zealand recycling processes:

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1. Information about our willingness and ability to provide congruent NIV Products and procurement options to healthcare providers funded by non-DHB entities, to enable continuity of patient care:

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| --- |
| *[eg. ACC, non-DHB community service and/or palliative care providers, other]* |

1. Information about how you envisage working with PHARMAC and other key stakeholders:

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| *[including how patients could obtain ongoing consumable requirements where DHB Hospitals provide initial NIV Products]* |

1. Proposal/suggestions (eg. pricing, risk sharing arrangements) regarding the medical device not expressly identified in this RFP that we would like PHARMAC to consider as part of our proposal:

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1. Reasons why PHARMAC should accept our proposal:

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1. Additional information that PHARMAC should consider when evaluating our proposal:

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