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10 May 2019

Dear Supplier

REQUEST FOR PROPOSALS - SUPPLY OF APOMORPHINE HYDROCHLORIDE, INFUSION PUMPS, DEDICATED PUMP SYRINGES (IF APPLICABLE) AND ASSOCIATED CONSUMABLES

PHARMAC invites proposals for the supply in New Zealand of apomorphine hydrochloride (that allows for both intermittent dosing regimens and continuous subcutaneous infusions) (**Apomorphine**), ambulatory infusion pumps and dedicated pump syringes (if applicable) (**Infusion Pumps**) and associated consumables (as described at 3(d) (ii) below). Together, Apomorphine and Infusion Pumps are referred to as "the Pharmaceutical".

This request for proposals (**RFP**) letter incorporates the following schedules:

- Schedule 1 specifies the Pharmaceutical for which PHARMAC is requesting proposals and sets out the background to the RFP and the types of proposals sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the RFP;
- Schedule 3 sets out information about the estimated size of the current subsidised market for the Pharmaceutical; and
- Schedule 4 contains the RFP form in which you are to provide details of your proposal(s).

If you wish to submit a proposal, you must submit it to PHARMAC via the Government Electronic Tender Service (**GETS**) www.gets.govt.nz no later than 4.00p.m. (New Zealand time) on **Friday 7 June 2019**

If you have any questions about this RFP, you should submit them via GETS, responses to all questions will be published on GETS.

We look forward to receiving your proposal.

Yours sincerely

Lisa Williams

Director of Operations

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Schedule 1: Pharmaceutical, background to RFP and types of proposals sought

1. Pharmaceutical

PHARMAC is interested in considering proposals for the supply of the Pharmaceutical (as defined on page 1 of this document), and the supply of the Pharmaceutical and associated consumables.

2. Background to RFP

The background to this RFP is as follows:

Apomorphine is a direct acting dopamine receptor agonist, structurally related to dopamine, and is typically used in the advanced stages of Parkinson's disease. Some patients receive Apomorphine as intermittent subcutaneous injections. However, as Parkinson's disease progresses symptoms tend to fluctuate and, as a result, patients may switch to Apomorphine continuous infusion. Some patients may continue to begin the day with a bolus dose followed by a continuous infusion set by a pump (currently provided by the supplier).

History of funding

Apomorphine 10 mg/ml, 2 ml ampoules (Movapo brand supplied by Stada Pharmaceuticals Australia Ltd) are currently listed in Section B and Part II of Section H of the Pharmaceutical Schedule without restrictions. Apomorphine has been listed on the Pharmaceutical Schedule since December 1996. The original listing was subject to Special Authority criteria relating to its use in Parkinson's disease and the applicant's specialty. It has been listed without restrictions on the Pharmaceutical Schedule since September 2006.

Since its listing, as far as PHARMAC is aware, the pump, the pump syringes (chrono syringes) and one month's supply of consumables (e.g. syringes, butterfly needles, filter needles) have been supplied free of charge to patients. Ongoing supply of consumables, PHARMAC understands, are then purchased by either the patient and/or the District Health Board (**DHB**).

Current funding

The table below outlines the current listing of apomorphine in Section B of the Pharmaceutical Schedule for use in the community.

	Subsidy/Price (NZ\$)	Per	Fully Subsidised	Brand or Generic Manufacturer
APOMORPHINE HYDROCHLORIDE				
Inj 10 mg per ml, 2 ml ampoule	 119.00	5	✓	Movapo

The table below outlines the current listing of apomorphine in Section H of the Pharmaceutical Schedule for use in DHB Hospitals.

	Subsidy/Price (NZ\$)	Per	Fully Subsidised	Brand or Generic Manufacturer
APOMORPHINE HYDROCHLORIDE				
Inj 10 mg per ml, 2 ml ampoule	 119.00	5	✓	Movapo

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Advice from the Neurological Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC).

PHARMAC sought clinical advice from the Neurological Subcommittee of PTAC at its meeting in September 2016 regarding a potential commercial process for apomorphine.

The key pieces of advice relevant to this RFP include advice on the various presentations of apomorphine, the clinical features of the ambulatory infusion pump, the use of associated consumables and the provision of a support service. Full details of the minutes are available on the PHARMAC website.

Reason for running the RFP

Apomorphine represents a significant expenditure to the Combined Pharmaceutical Budget (**CPB**). For the 2018 financial year (1 July 2017–30 June 2018), the approximate expenditure on Apomorphine was \$3.4 million.

There are currently no rebates applied to Apomorphine.

PHARMAC is aware of several brands of apomorphine currently registered with Medsafe or available overseas. In view of this competition, the purpose of this RFP is:

- (a) to reduce the total expenditure in the Apomorphine market; and
- (b) to secure supply of the funded Pharmaceutical for three years; and
- (c) to determine if funded access to associated consumables would be possible from within the available budget.

Any proposals progressed for consideration for funding would be assessed using PHARMAC's decision-making framework as outlined in its Operating Policies and Procedures (**OPP**s) with reference to the <u>Factors for Consideration</u> (**Factors**).

3. Types of proposals sought

Suppliers MUST submit proposals for community and hospital supply of the Pharmaceutical.

- (a) All proposals MUST include:
 - (i) Apomorphine, in a presentation(s) that allows for both intermittent dosing regimens and continuous subcutaneous infusions via a pump.
 - (ii) Infusion Pumps (as defined on page1). PHARMAC does not expect that these would be listed individually on the Pharmaceutical Schedule. The supplier would be required to provide the Infusion Pump directly to patients and/or healthcare professionals responsible for assisting with the administration of Apomorphine. In addition, suppliers must provide full details regarding distribution of the Infusion Pump to patients and/or healthcare professionals responsible for assisting with the administration of apomorphine, warranties, repair and replacement of the Infusion Pumps.
 - (iii) a period of three years of sole subsidised supply of the Pharmaceutical in the community and hospital supply status in DHB Hospitals (subject to a 1% DV limit) (hereinafter referred to as "**Sole Supply**"), provided that the Sole Supply period does not extend beyond 30 June 2023.

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- (iv) details of patient support services that would be offered.
- (v) details of clinical support and training
- (b) All proposals that require a brand change of Apomorphine MUST include:
 - (i) an option that permits the Movapo brand of Apomorphine to continue to be used for patients who have a clinical reason that would prevent them changing (e.g. an allergic reaction) to the new product.
 - (ii) a six-month transition period between listing the new brand of the Pharmaceutical and commencement of any Sole Supply arrangement; and
 - (iii) a comprehensive detailed transition plan to support a brand switch

Proposals MAY include:

- (i) Pharmaceuticals that have not yet gained all necessary consents "Consents" mean all consents, permits, licences and authorisations, whether statutory or otherwise, required for the supply of the Pharmaceutical in New Zealand (including Ministry of Health market approval). In these circumstances, suppliers may be required to demonstrate the ability to obtain those consents within a time frame acceptable to PHARMAC;
- (ii) rebates that have a flat (per unit) rebate structure;
- (iii) two or more presentations of Apomorphine, provided that at least one of the presentations is suitable for intermittent dosing regimens and at least one of the presentations is suitable for continuous subcutaneous infusions via an Infusion pump;
- (iv) if a supplier wishes to include a pre-filled syringe/pen as part of a proposal, for example a proposal that included a pre-filled syringe/pen for intermittent dosing and a vial for use in continuous subcutaneous infusions, the supplier MUST also provide a separate proposal that does not include a prefilled syringe/pen but instead includes a presentation(s) of apomorphine that would be suitable for intermittent and continuous dosing regimens via an infusion pump. For example, a 10ml vial (provided that this is suitable for both intermittent and continuous infusions); or, a 10ml vial and a 2ml ampoule (provided that at least one of these is suitable for intermittent dosing and at least one of these is suitable for continuous infusions).
- (c) Suppliers MAY also submit proposals for community and hospital supply of the Pharmaceutical and associated consumables. A supplier may submit a proposal for the Pharmaceutical and associated consumables provided that the supplier has also submitted a separate proposal solely for the Pharmaceutical.
 - (i) Where a proposal includes associated consumables, PHARMAC does not expect that these associated consumables would be listed, as a result of this RFP, individually on the Pharmaceutical Schedule. The supplier would be required to provide the Infusion Pump and associated consumables and would need to detail what associated consumables they would be providing

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under this arrangement. In addition, suppliers must provide full details regarding distribution of the Infusion Pump and associated consumables to patients and/or healthcare professionals responsible for assisting with the administration of Apomorphine, warranties, repair and replacement of the pumps.

- (ii) Types of associated consumables may depend on the presentation of the apomorphine supplied. Examples include (but are not limited to):
 - sterile needles;
 - subcutaneous infusion needles;
 - alcohol swabs:
 - syringes;
 - syringe spacers; and
 - adhesive tape (if required for attachment of subcutaneous infusion needles); and batteries.
- (iii) If as a result of this RFP, DHB Hospitals are required to purchase associated consumables for the Pharmaceutical that are not included as part of a supplier's proposal and are not currently listed on the Pharmaceutical Schedule. PHARMAC may, at its option list, these consumables on the Pharmaceutical Schedule.
- (vi) Suppliers should provide PHARMAC with samples of the Apomorphine presentations, Infusion Pumps and consumables (if applicable) included in their proposal (and, if supply is intended to be in a different presentation, form and strength from the provided samples, information about those differences) within 10 business days from the dated specified in Schedule 2, clause 1(b).
- (e) PHARMAC is **NOT** willing to consider the following types of proposals:
 - (i) proposals that include pharmaceuticals other than Apomorphine;
 - (ii) proposals that involve restricting access;
 - (iii) proposals that do not include an Infusion Pump;
 - (iv) proposals that would incur a direct cost to the patient for access to the Infusion Pump and any associated consumables included in the proposal.
 - (v) proposals that do not include the dedicated pump syringe where a dedicated pump syringe is necessary to the operation of the ambulatory infusion pump;
 - (vi) proposals that include devices or consumables other than those necessary for the infusion of apomorphine;
 - (vii) proposals that involve foreign currency exchange rate clauses or prices linked to any index;
 - (viii) proposals that involve the listing of the Infusion Pump and/or its associated consumables in the Pharmaceutical Schedule; or

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(ix) proposals that involve expenditure caps.

Subject to the above, PHARMAC is open to considering any other types of proposals that you may wish to put forward.

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Schedule 2: RFP process

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

1. Submission

- (a) You may submit more than one proposal. Each proposal will be considered as a separate proposal.
- (b) Proposals must be submitted to PHARMAC via the Government Electronic Tender Service (GETS) no later than 4.00p.m. (New Zealand time) on 7 June 2019. Late proposals will only be considered at PHARMAC's discretion, taking into account the need for fairness to other suppliers and the integrity of the RFP process.
- (c) You cannot withdraw your proposal, once submitted, while the RFP process is continuing.
- (d) If you have any enquiries about this RFP, you should submit them via GETS, responses to all enquires will be published on GETS.

2. Evaluation

- (a) Following the deadline for submitting proposals, an Evaluation Committee comprising PHARMAC staff will evaluate each proposal to select its preferred proposal(s).
- (b) The Evaluation Committee will evaluate proposals 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 that form part of PHARMAC's current OPPs, as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable. More information on the Factors can be found at www.pharmac.health.nz/factors-for-consideration.
- (c) The requirement for PHARMAC to pursue its statutory objective means that emphasis will be given to those aspects of proposals which demonstrate "health outcomes", and those aspects of proposals which demonstrate the impact on the "funding provided" for pharmaceuticals. Those Factors which relate directly to these aspects will be given the greatest weight by the Evaluation Committee, but all Factors are important.
- (d) The information to be taken into account in applying the Factors by the Evaluation Committee will be at its discretion, however it will include:
 - (i) information provided by you in accordance with Schedule 4 of this RFP, including information provided under clause 3 below;
 - (ii) any advice from the Pharmacology and Therapeutics Advisory Committee (PTAC), its relevant subcommittee, any relevant professional organisation or healthcare professionals; and
 - (iii) any other information that the Evaluation Committee considers to be relevant having regard to probity principles.

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- (e) Each proposal will be evaluated on the basis that the price offered, the expenditure entailed, and any other terms included in the proposal, are the best that the supplier is able to offer. If you do not put forward your best terms you risk having your proposal excluded at the evaluation stage.
- (f) PHARMAC is not bound to select the lowest priced proposal, or any proposal.

3. PHARMAC may request further information

- (a) PHARMAC may request such further information as it considers necessary from or about you for the purposes of clarifying or evaluating your proposal, including (but not limited to):
 - (i) detailed information about your company structure, credit status and any other relevant company information; and
 - (ii) any other additional information about the Pharmaceutical, or associated consumables.

Please note that PHARMAC may seek advice from PTAC, its relevant Subcommittee, any relevant professional organisations or healthcare professionals with regards to your product, including evaluation of any product samples.

(b) If PHARMAC requests further information from or about you, 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. Negotiation

- (a) PHARMAC may negotiate with the submitter(s) of one or more preferred proposals, in the latter case whether or not the acceptance of either supplier's proposal would exclude acceptance of the other proposal.
- (b) Negotiations will proceed on the basis that PHARMAC's standard terms and conditions for supply of pharmaceuticals, which are available on request from PHARMAC, will apply.
- (c) Given that PHARMAC expects your proposal to be the best you can offer, PHARMAC does not intend to initiate negotiation with you on price. However, PHARMAC does not exclude the possibility that the final price agreed will be different from the price put forward in your proposal, as a result of the impact that other negotiated terms may have on price.
- (d) PHARMAC may negotiate and enter into a provisional agreement with a preferred supplier(s) on whatever special terms, in addition to PHARMAC's standard terms and conditions, PHARMAC considers appropriate.
- (e) If PHARMAC and the supplier(s) are unable to reach a provisional agreement within what PHARMAC considers to be a reasonable time, PHARMAC may terminate those negotiations and negotiate with a different supplier(s).

5. **Consultation and approval**

(a) Any provisional agreement will be conditional on consultation with suppliers and other interested parties, to the extent PHARMAC considers consultation to be

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- necessary or appropriate, and on Board approval (or approval by the Board's delegate acting under delegated authority).
- (b) PHARMAC will not consider any counter-offers received during consultation.
- (c) The provisional agreement and responses to consultation will be considered by PHARMAC's Board (or by the Board's delegate acting under delegated authority) in accordance with PHARMAC's decision-making framework as outlined in its OPPs with reference to the Factors.
- (d) If the Board or its delegate does not approve the provisional agreement, then PHARMAC may initiate negotiations for a provisional agreement with any other supplier(s).
- (e) The RFP process will be complete once PHARMAC has notified suppliers of either:
 - (i) the Board's or its delegate's decision to accept a negotiated agreement; or
 - (ii) the termination of the RFP process.

6. Miscellaneous

- (a) PHARMAC reserves the right, having regard to probity principles:
 - (i) to make such adjustments to the above RFP process as it considers appropriate, at any time during the process, provided that it notifies suppliers affected by those changes;
 - (ii) not to accept any proposal;
 - (iii) to seek clarification of any proposal;
 - (iv) to meet with any supplier in relation to its proposal(s);
 - (v) to enter into an agreement or arrangement that differs in material respects from that envisaged in this RFP;
 - (vi) to suspend this RFP process. For example, if during the RFP process (and before a provisional agreement is entered into) it becomes apparent to PHARMAC that further consultation is appropriate or required, PHARMAC may suspend the RFP process in order to consult. In this situation, PHARMAC may ask you to adapt and resubmit your proposal in light of consultation, or alternatively PHARMAC may request that new proposals be submitted:
 - (vii) to terminate this RFP process at any time, by notifying suppliers who submitted proposals, and, following termination, to negotiate with any supplier(s) on whatever terms PHARMAC thinks fit; and
 - (viii) to re-advertise for proposals.
- (b) PHARMAC may consult or seek clinical advice from PTAC or its relevant subcommittee at any stage of the RFP process. PHARMAC will notify you if the clinical advice results in any changes to the terms of the RFP.

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- (c) You must not initiate or engage in any communication with other suppliers in relation to the RFP, whether before or after submitting your proposal(s), until such time as a provisional agreement is accepted by PHARMAC's Board or the Board's delegate.
- (d) You must not at any time initiate any communication with PHARMAC, the Ministry of Health (including its operating unit Medsafe), the Minister of Health (or any Associate Ministers) or District Health Boards or advisors to PHARMAC with a view to influencing the outcome of this RFP process.
- (e) You must pay your own costs for preparing and submitting your proposal(s).
- (f) Proposals are submitted in reliance on your own knowledge, skill, and independent advice, and not in reliance on any representations made by PHARMAC.
- (g) Your submission of a proposal will be taken as acceptance of the terms contained in this RFP. PHARMAC may exclude your proposal if you do not comply with any of the terms contained in this RFP.
- (h) This is an RFP and not a tender. Your proposal is not an offer capable of being converted into a contract for the supply of the Pharmaceutical or the supply of the Pharmaceutical and associated consumables by PHARMAC's apparent acceptance and instead a separate agreement needs to be negotiated.
- (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 you or any other person in relation to this RFP.
- (j) PHARMAC will consider your proposal and information exchanged between us in any negotiations relating to your proposal, excluding information already in the public domain, to be confidential to us and our employees, legal advisors and other consultants, the Ministry of Health and DHBs (**Confidential Information**). However, you acknowledge that it may be necessary or appropriate for PHARMAC to release Confidential Information:
 - (i) pursuant to the Official Information Act 1982; or
 - (ii) in the course of consultation on a provisional agreement entered into with a supplier; or
 - (iii) in publicly notifying any approval by the PHARMAC Board of that agreement; or
 - (iv) otherwise pursuant to PHARMAC's public law or any other legal obligations.

PHARMAC may consult with you before deciding whether to disclose Confidential Information for the purposes described in sub-clauses (i) to (iv) above. You acknowledge, however, that it is for PHARMAC to decide, in its absolute discretion, whether it is necessary or appropriate to disclose Confidential 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 proposals, PHARMAC anticipates:

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- (i) the Evaluation Committee evaluating proposals in June 2019;
- (ii) seeking clinical advice (if necessary) in June 2019;
- (iii) negotiating with submitter(s) of one or more preferred proposals in June/July 2019;
- (iv) consulting on any provisional agreement in July 2019;
- (v) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in or after July/August 2019.

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

- (b) Under this indicative timetable, PHARMAC expects the earliest that changes to the Pharmaceutical Schedule could be implemented is September 2019.
- (c) Please note that if a proposal for Sole Supply is accepted, the date of implementation may be later to allow for an orderly transition to any Sole Supply arrangement.

8. Governing Law

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

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Schedule 3: Current listing and market information

The following information relates to the estimated subsidised market size of apomorphine. The information is approximate and indicative only. PHARMAC makes no representation as to the accuracy of this information or as to the level of sales or likely sales of apomorphine and, while PHARMAC has taken all reasonable care in preparing the information set out below, it accepts no liability for any errors or omissions in the information. PHARMAC is not obliged to notify you in the event of any change to the figures below.

1. Usage of apomorphine

Usage of apomorphine (number of individual units and net expenditure) in the community for the 2016, 2017 and 2018 financial years is shown in the following table.

Inj 10mg per ml, 2ml ampoule	FYE 30 June 2016	FYE 30 June 2017	FYE 30 June 2018	YTD July 2018 to 31 December 2018
Units	94,488	113,562	143,772	122,647
Expenditure	\$2,248,814	\$2,702,776	\$3,421,774	\$2,918,999

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Schedule 4: Proposal form

An electronic version of this form is available on GETS (<u>www.gets.govt.nz</u>). You should expand the boxes as necessary.

[Supplier to insert date]

Director of Operations PHARMAC C/- Jeremy Price

By electronic transfer using GETS (https://www.gets.govt.nz)

Dear Sir/Madam

Proposal for the supply of Apomorphine, Infusion Pumps and associated consumables – commercial in confidence

In response to your request for proposals (**RFP**) dated 10 May 2019 we put forward the following proposal in respect of the supply of the Pharmaceutical (as defined in the RFP). Set out below is further information in support of our proposal.

(a) Our contact details:

Name of supplier	
Contact person	
Address	
Phone	
Facsimile	
Email address	

(b) Details of Apomorphine presentation(s):

Chemical name	
Strength e.g. 10mg per ml	
Forms (e.g. ampoule/ vial)	
Brand name	
Pack size (e.g. 5 vials)	
Packaging type (e.g. prefilled syringe)	
Shelf life (e.g. 36 months from date of manufacture stored at or below 30°C)	

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Name and address of manufacturer/s of the pharmaceutical (including API manufacturer, manufacturer of final dose form, packaging etc) Lead time (Time from notification of award to product being available to supply the New Zealand	
pharmaceutical (including API manufacturer, manufacturer of final dose form, packaging etc) Lead time (Time from notification of award to product being available to	
API manufacturer, manufacturer of final dose form, packaging etc) Lead time (Time from notification of award to product being available to	
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Lead time (Time from notification of award to product being available to	
notification of award to product being available to	
product being available to	
. •	
supply the New Zealand	
market)	
Details on pharmaceutical	
manufacturing sites and	
their registration with	
Medsafe or other	
international regulatory body (e.g. TGA, FDA, MHRA)	
Batch size/s	
Approximate manufacture	
time	
Approximate time for	
Approximate time for	
shipping Details of Infusion Pump(s) pro	esentation:
shipping	resentation:
shipping Details of Infusion Pump(s) pro	resentation:
shipping Details of Infusion Pump(s) product name	resentation:
Shipping Details of Infusion Pump(s) properties Product name Brand name	resentation:
Shipping Details of Infusion Pump(s) pro Product name Brand name Guarantee period	resentation:
Details of Infusion Pump(s) product name Brand name Guarantee period Maintenance requirements	resentation:
Details of Infusion Pump(s) product name Brand name Guarantee period Maintenance requirements Batteries number and type Dedicated pump syringe	resentation:
Product name Brand name Guarantee period Maintenance requirements Batteries number and type Dedicated pump syringe (where applicable) Functions (e.g. flow rates,	resentation:
Details of Infusion Pump(s) product name Brand name Guarantee period Maintenance requirements Batteries number and type Dedicated pump syringe (where applicable) Functions (e.g. flow rates, bolus size, battery life) List standard equipment supplied with pump	resentation:
Product name Brand name Guarantee period Maintenance requirements Batteries number and type Dedicated pump syringe (where applicable) Functions (e.g. flow rates, bolus size, battery life) List standard equipment	

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	exclusive),	including	any r
and an	y other re	quired con	sents fo
copy of			
	and an	and any other recopy of	and any other required con

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Confirmation that there are no intellectual property barriers (including pate barriers) to our supply of the Pharmaceutical in New Zealand, with addition information if required:
Information about our ability to ensure the continuity of supply of Pharmaceutical, including other countries where it is provided:
Information about our previous supply performance, existing commitments a relevant expertise:
Tolovani experies.
Proposals/suggestions regarding the Pharmaceutical not expressly identified in t RFP that we would like PHARMAC to consider as part of our proposal:
Reasons why PHARMAC should accept our proposal:

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	is an outline of how our company would manage a recall of the Inf) and or deal with/replace a damaged Infusion Pump(s):
	s an outline our company's resourcing for patient support and clinical ion and training:
Below	is a detailed transition plan of what we would do to support a brand cha
consun	se we have submitted a proposal for the Pharmaceutical and associate nables, below is a list of the individual associated consumables we wou for the administration of Apomorphine via an Infusion Pump:

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(r)	Below are details of our processes for distribution of the Infusion Pumps, and associated consumables (if submitting a proposal for the Pharmaceutical and associated consumables) to patients and/or healthcare professionals responsible for administration of Apomorphine:
(0)	Below is additional information that PHARMAC should consider when evaluating
(s)	our proposal, including information we consider relevant under PHARMAC's Factors for Consideration decision-making framework:

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