

[Date]

[Name and address]

Dear []

TERMS OF LISTING OF MEDICAL DEVICES, SUPPLIED BY [insert supplier name], ON THE PHARMACEUTICAL SCHEDULE

Pharmac agrees to:

- [list in Section H, Part III of the Pharmaceutical Schedule, with effect from [insert date], the Medical Devices listed or referenced in Schedule 1;]
- [amend, with effect from [insert date], the terms on which the Medical Devices, listed or referenced in Schedule 1, are listed in Section H, Part III of the Pharmaceutical Schedule;]

on the terms set out in this letter and the attached Parts, Schedules and Annexures (together forming this “**Agreement**”).

In this Agreement:

- “**Medical Device**” means the medical devices listed or referenced in Schedule 1 and “**medical device**” means any medical device that Pharmac is able to list, all of which are therapeutic medical devices and hence pharmaceuticals within the meaning of the Pae Ora (Healthy Futures) Act 2022;
- “**Section H, Part III**” means the relevant part of the Pharmaceutical Schedule where medical devices are listed;
- references to the “**listing**” of a Medical Device are to the listing of that Medical Device in Section H, Part III of the Pharmaceutical Schedule and are deemed to include any written notification by Pharmac of that Medical Device being the subject of a national supply contract negotiated by Pharmac on behalf of Te Whatu Ora, where such written notification is in advance of the actual listing of that Medical Device in Section H, Part III of the Pharmaceutical Schedule (and references to “list”, “listed”, “delist”, “delisted”, and “delisting” are to be interpreted accordingly);
- reference to “**supply**” of a Medical Device is not limited to the sale of a Medical Device by you and also means the consignment of a Medical Device and the supply of a Medical Device on a Loan basis (and references to “supplied” are to be interpreted accordingly);
- references to “**procurement**” of a Medical Device by a Te Whatu Ora Hospital or a Logistics Provider is not limited to the purchase of a Medical Device and also means the procurement of Consignment Medical Devices and Loan Medical Devices (and references to “procure” and “procured” are to be interpreted accordingly);
- references to “**Te Whatu Ora**” encompass Te Whatu Ora Hospitals; and

- references to “**Te Whatu Ora Hospitals**” may reflect that certain operational matters can in practice occur at a local hospital level notwithstanding that Te Whatu Ora Hospitals are part of, and not separate legal entities from, Te Whatu Ora .

Parts

The following Parts of this Agreement set out terms relating to:

- Part 1: the role of Pharmac and the Te Whatu Ora Hospitals in relation to this Agreement;
- Part 2: your general obligations and warranties in relation to the supply of Medical Devices;
- Part 3: ordering and delivering of the Medical Devices;
- Part 4: the price of and payment for the Medical Devices;
- Part 5: reporting and audit;
- Part 6: supply obligations and Failure to Supply;
- Part 7: other general terms;
- Part 8: any special terms; and
- Part 9: any special terms for each Category of Medical Device.

Schedules

- Schedule 1 defines (or references material that defines) each Medical Device, describes (or references material that describes) each Medical Device, and specifies (or references material that specifies) the Price at which each Medical Device is to be supplied or sold, or made available for supply or sale, by you to, at a Te Whatu Ora Hospital’s discretion, its required delivery point and the price at which that Medical Device can be procured by Te Whatu Ora Hospitals, unless another price is determined under Part 8 and/or Part 9.
- Schedule 2 sets out any Product Specifications for any Medical Device being supplied pursuant to this Agreement.
- Schedule 3 sets out the performance standards and reporting requirements applicable to this Agreement.
- Schedule 4 sets out the contact details of the parties.

Precedence

In this Agreement, the following order of precedence will apply in the event of any ambiguity, inconsistency, or conflict of obligations:

- Part 9;
- Part 8;
- Schedules;
- Parts 1 to 7.

Acceptance

To confirm your acceptance of this Agreement please sign a copy and return it to Pharmac (electronically or by hard copy) by [] pm on [insert date].

Yours faithfully

[]

Signed and agreed by [insert name of medical device supplier] by:

Name:

Position:

Date:

PART 1: Role of Pharmac and the Te Whatu Ora Hospitals

1. Pharmac's Role

1.1 Overview of Pharmac's role

- (a) In accordance with the Pae Ora (Healthy Futures) Act 2022, Pharmac maintains and manages the Pharmaceutical Schedule within the amount of funding provided to it, which includes determining eligibility and criteria for the provision of subsidies.
- (b) Over time Pharmac will assume responsibility for managing the prioritisation, assessment, standardisation and procurement of medical devices. Initially, Pharmac has responsibility for the procurement of some medical device categories on behalf of Te Whatu Ora, including the category that each Medical Device falls under.
- (c) This Agreement is a listing agreement whereby Pharmac agrees to list certain Medical Devices on the Pharmaceutical Schedule and stipulates the terms upon which you may supply those Medical Devices to Te Whatu Ora. As such, your contractual relationship is with Pharmac even though your supply of Medical Devices is ultimately for the benefit of Te Whatu Ora, who will place orders and make payment for such Medical Devices, either directly or through a Logistics Provider.

1.2 Use of the Operating Policies and Procedures

- (a) You acknowledge that:
 - (i) Pharmac is required to pursue the objectives, carry out the functions, and otherwise comply with the statutory obligations, prescribed for Pharmac in the Pae Ora (Healthy Futures) Act 2022;
 - (ii) Pharmac is subject to other statutory and public law obligations, which govern Pharmac's decision-making processes;
 - (iii) Pharmac has Operating Policies and Procedures ("**OPPs**"), which provide guidance on the way in which Pharmac carries out its statutory responsibilities in relation to the management of the Pharmaceutical Schedule;
 - (iv) Pharmac's OPPs may be amended or updated from time to time, following consultation with relevant groups;
 - (v) the actions which Pharmac may take under its OPPs include (without limitation):
 - (A) listing new therapeutic medical devices;
 - (B) changing guidelines or restrictions on the purchasing of listed medical devices (including new therapeutic medical devices);
 - (C) changing the market dynamics for therapeutic medical devices as a result of Pharmac adopting one of the strategies set out in the OPPs;
 - (vi) any action taken by Pharmac pursuant to its OPPs may impact on the listing of each Medical Device.

- (b) Pharmac agrees not to apply, amend or update its OPPs in order to avoid any of Pharmac's obligations under this Agreement.

1.3 Agreement conditional on consultation and Pharmac approval

- (a) This Agreement is conditional on:
 - (i) Pharmac completing all consultation it considers necessary or appropriate (including consultation under its Operating Policies and Procedures); and
 - (ii) following consultation, approval of its terms by Pharmac's Board (or by its delegate acting under delegated authority pursuant to section 73 of the Crown Entities Act 2004, where applicable).
- (b) You may withdraw from this Agreement, or negotiate with Pharmac to amend its terms, if consultation or a decision of Pharmac's Board results in a material change to the terms of this Agreement.

1.4 Listing Medical Devices in the Pharmaceutical Schedule

- (a) Each Medical Device to be listed by Pharmac, or in respect of which amendments are to be made by Pharmac to any current listing on the Pharmaceutical Schedule, as set out in the letter at the start of this Agreement, falls into a particular Category of Medical Device as set out in Part 8 and/or Part 9 of this Agreement.
- (b) You are not permitted to supply any medical device to a Te Whatu Ora Hospital that is not listed on the Pharmaceutical Schedule, if the therapeutic purpose of that medical device is similar to the therapeutic purpose of a Medical Device that is listed, without first notifying Pharmac and without Pharmac's express written consent, such consent not to be unreasonably withheld.
- (c) Pharmac will consult with you before amending Section H, Part III of the Pharmaceutical Schedule either, at Pharmac's discretion, through a general consultation process involving multiple suppliers or individually with you, if a proposed amendment would materially affect the listing of a Medical Device.

1.5 Product Specifications

Where the relevant column listed or referenced in Schedule 1 indicates that a Product Specification applies to a Medical Device, the relevant Product Specification, as evidenced by the identification number in the relevant column listed or referenced in Schedule 1 and as described in Schedule 2, applies to that Medical Device and any such Medical Device supplied by you pursuant to this Agreement must conform with the relevant Product Specification.

1.6 Additional services

Part 8 and/or Part 9 of this Agreement include(s) any additional services that you must provide in conjunction with the supply of a particular Category of Medical Device.

1.7 Meetings and contract manager

- (a) You agree to provide any information reasonably requested by Pharmac in respect of a matter connected with this Agreement and to actively participate in a constructive manner in any meeting that takes place between the parties in respect of this Agreement.
- (b) You agree to ensure that Pharmac is informed of your nominated contract manager at all times and of any changes to such nominated contract manager from time to time. The role of your nominated contract manager is:
 - (i) to take responsibility for the overall management of this Agreement including attaining or implementing agreed performance standards and supply chain initiatives as well as coordinating communication between the parties;
 - (ii) working with Pharmac (and as applicable each Te Whatu Ora Hospital and Logistics Provider) on service initiatives and in providing market information to ensure that the Te Whatu Ora Hospital's needs can be aligned with the commercial supply environment; and
 - (iii) to co-operate with Pharmac Personnel in the event of a Failure to Supply.

2. Role of the Te Whatu Ora Hospitals

- (a) The Te Whatu Ora Hospitals' principal role in respect of this Agreement is to place Purchase Orders with you, make payment to you for the Medical Devices procured, and take delivery of Medical Devices procured.
- (b) Your day to day contact in respect of the supply of Medical Devices will be with representatives from each Te Whatu Ora Hospital (as notified by each Te Whatu Ora Hospital from time to time) but, consistent with clause 9.1(b) of this Agreement, your contractual relationship is with Pharmac (subject to the application of provisions relating to privity of contract for the benefit of Te Whatu Ora Hospitals as set out in this Agreement).

3. Logistics Provider

- (a) A Te Whatu Ora Hospital may at any time decide or be required to utilise the services of a Logistics Provider to procure any Medical Devices.
- (b) A Logistics Provider may be responsible for placing Purchase Orders with you, for making payment to you for the Medical Devices procured, and for taking delivery of Medical Devices.
- (c) If a Te Whatu Ora Hospital utilises the services of a Logistics Provider to procure a Medical Device, your day to day contact in respect of the supply of that Medical Device will be with the Logistics Provider rather than the relevant Te Whatu Ora Hospital.

4. Supplier contacts

4.1 Liaison person for Purchase Orders and delivery

- (a) You will ensure that at all times you have a liaison person appointed to liaise with Te Whatu Ora Hospitals and any Logistics Provider (as applicable) in respect of the

procurement, payment and delivery of Medical Devices. Relevant contact details for liaison person(s) are listed in Schedule 4 of this Agreement.

- (b) You will notify each Te Whatu Ora Hospital and Logistics Provider of any changes to the relevant liaison person from time to time.

4.2 **Medical Device queries**

- (a) You will make available to each Te Whatu Ora Hospital a New Zealand telephone number at which you can be contacted:
 - (i) between the agreed hours stated in Part 8 and/or Part 9 to provide support and answer any general questions relating to a Medical Device that the Te Whatu Ora Hospital may have (including, where applicable, providing assistance to identify and rectify a fault in any Medical Device); and
 - (ii) on a 24-hours a day, seven (7) days a week basis for any trouble-shooting support relating to the use of a Medical Device, subject to any limitations or exceptions specified in Part 8 and/or Part 9.

These are the contact number(s) to be listed in Schedule 4 of this Agreement.

- (b) You will ensure that appropriately qualified personnel are available to provide the support described in (a) to the Te Whatu Ora Hospital.
- (c) The support described in (a) will be provided at no cost to the Te Whatu Ora Hospital unless otherwise indicated in Part 8 and/or Part 9 in respect of a particular Medical Device.

5. **Crown Direction**

- (a) You acknowledge that Pharmac must comply with any Crown Direction.
- (b) Pharmac may terminate or amend this Agreement, or impose restrictions on the use of a Medical Device, at any time, if the termination, amendment or imposition of restrictions is required to give effect to a Crown Direction.
- (c) In the event that a Crown Direction is issued to Pharmac that requires an amendment to be made to this Agreement to give effect to that direction:
 - (i) Pharmac will give you as much notice as practicable of the Crown Direction and of any amendments to this Agreement that are required to give effect to that direction;
 - (ii) Pharmac may consult with you, at its option, on any actions which can be implemented to give effect to that direction; and
 - (iii) this Agreement will be deemed to be amended so as to give effect to the Crown Direction from the date when such direction is due to take effect.

6. **Pharmac's rights reserved regarding patient safety**

Notwithstanding any other provision of this Agreement, and without prejudice to any other of Pharmac's legal rights and remedies, whether under this Agreement or otherwise, Pharmac reserves the right at any time to take any action in relation to the listing of a Medical Device, or the basis on which it is listed, including (without limitation):

- (a) changing or imposing restrictions on the use of a Medical Device;
- (b) delisting a Medical Device;
- (c) terminating this Agreement; and/or
- (d) any other action that Pharmac decides, in its sole discretion, is necessary or appropriate,

without your agreement, in accordance with any direction from Medsafe, or recommendation from PTAC, or relevant PTAC sub-committee, or medical device advisory committee, based on patient safety.

PART 2: General obligations and warranties

7. Warranties

7.1 Medical Device Warranties

You warrant that any Medical Device supplied to a Te Whatu Ora Hospital (or Logistics Provider, if applicable) under this Agreement will:

- (a) comply with the specifications set out in any Product Specification that applies to the relevant Medical Device;
- (b) be notified on the Web Assisted Notification of Devices (“WAND”) Medsafe Database or to any other relevant authority;
- (c) be supplied in accordance with any minimum shelf life specified in Part 8 and/or Part 9 applicable to the relevant Medical Device;
- (d) comply with any current Standards New Zealand or industry codes of practice applicable to the relevant Medical Device;
- (e) to the extent applicable to the relevant Medical Device, comply with Good Manufacturing Practice (GMP) procedures and Infection Control Standards;
- (f) be manufactured to ISO or TGA or CE or FDA standards and be approved by the relevant regulatory agencies;
- (g) be delivered free of any encumbrance, adverse interest or claim by any third party;
- (h) have clear and indelibly inscribed labels in English;
- (i) be new, of a high standard, of merchantable quality, manufactured in accordance with best industry practice, free from faults and defects and fit for the Medical Device’s intended purpose; and
- (j) if requested by Pharmac, Te Whatu Ora, or the agent of Te Whatu Ora obtain a Global Trade Item Number (GTIN) (“Code”) that applies to the relevant Medical Device. In this event you will obtain the Code within 6 (six) months and you will notify the requester of the Code assigned.

7.2 General Supplier Warranties

In addition to any of the Medical Device warranties provided under this Agreement, you warrant that you operate a Quality Management System that complies with the requirements of ISO 9001 or ISO 13485.

8. Special warranties

- (a) Part 8 and/or Part 9 sets out any additional warranties that are specific to a Category of Medical Device.

- (b) Part 8 and/or Part 9 sets out any additional warranties that are particular to a specific Medical Device.
- (c) Part 8 and/or Part 9 sets out any exclusions from any of the general or special warranties that Pharmac has agreed to in respect of that specific Medical Device.

9. General obligations

9.1 Supply of Medical Devices

- (a) You will supply and deliver each Medical Device, as and when required by any Te Whatu Ora Hospital or Logistics Provider (as applicable), in accordance with the terms of this Agreement.
- (b) You agree that you will not offer any special terms and conditions (including, but not limited to, price discounts or rebates for bulk purchasing) in respect of any Medical Device to any Te Whatu Ora Hospital or Logistics Provider (if applicable) outside of the terms and conditions of this Agreement without Pharmac's prior written approval.

9.2 Emergency and disaster supply

In the event of an emergency or disaster that impacts on any Te Whatu Ora Hospital or its requirements, or an emergency or disaster on a national level, you will use your best endeavours to provide such quantities of the Medical Devices as are required by the relevant Te Whatu Ora Hospital(s) or Logistics Provider (as applicable). Your obligations under this clause include, but are not limited to, using your best endeavours to:

- (a) source the Medical Devices from other suppliers and distributors within New Zealand; and
- (b) source the Medical Devices or Alternative Medical Devices from any overseas manufacturer, supplier or distributor, and air-freighting that stock to New Zealand (for which the relevant Te Whatu Ora Hospital or Logistics Provider (as applicable) will meet all reasonable costs, provided that these costs have been notified to the Te Whatu Ora Hospital or Logistics Provider (as applicable) in advance) for supply to Te Whatu Ora Hospitals or Logistics Providers, as applicable. This clause is subject always to obtaining Pharmac's approval to supply any replacement medical device that is not identical to the relevant Medical Devices.

9.3 Permits and standards

- (a) You must maintain all necessary rights and Permits to supply the Medical Devices (and any related services) to Te Whatu Ora and Logistics Providers (if applicable). If a necessary right or Permit is not held by you or is withdrawn, or a Medical Device is no longer able to be supplied in New Zealand for any reason (including where the Director-General has issued an order pursuant to the Medicines Act or regulations made pursuant to that Act, directing the withdrawal from sale of the Medical Device), then:
 - (i) Pharmac is entitled to terminate all or part of this Agreement by fourteen (14) days' written notice to you; and
 - (ii) you acknowledge and agree that the provisions of clauses 27.2, 28.2 and 28.3 of this Agreement are to apply notwithstanding such termination.

- (b) You must ensure that the Medical Devices comply with all applicable specific standards, codes of practice, regulations and statutory requirements, including without limitation those listed in Part 8 and/or Part 9 of this Agreement.

9.4 Compliance with laws and standard of products and services

- (a) You must carry out your obligations under this Agreement with reasonable care, skill and diligence and will employ techniques of a high quality and will employ any relevant standards (including those referred to in clause 11 of this Agreement), in accordance with best industry practice and in accordance with all applicable laws.
- (b) You must ensure that any of your Personnel involved in providing any services under or in connection with this Agreement are:
 - (i) competent, appropriately qualified and, where relevant, registered with or licensed by the appropriate statutory or professional body; and
 - (ii) adequately trained and supervised in the safe use of all machinery, tools, processes, substances, protective clothing and equipment, which they may be required to use in relation to the supply of the services.

9.5 Proprietary rights

You must remain the owner or licensee of all the proprietary rights and Intellectual Property Rights in the Medical Devices and any related services and must ensure that:

- (a) you are not in breach of any Intellectual Property Rights of any third party; and
- (b) the Te Whatu Ora Hospital's and its Personnel's possession and use of the Medical Devices will not infringe any Intellectual Property Rights of any third party.

9.6 Shelf-life of products

- (a) You will not supply a Medical Device if the remaining shelf-life of that Medical Device is less than any amount that may be specified in Part 8 and/or Part 9 in respect of a particular Medical Device, without prior agreement from the relevant Te Whatu Ora Hospital.
- (b) If you have an agreement with the relevant Te Whatu Ora Hospital to supply a Medical Device, where the total shelf-life of that Medical Device is less than the amount specified in Part 8 and/or Part 9, and that Te Whatu Ora Hospital does not use that Medical Device before its expiry or use-by date, you agree to allow that Te Whatu Ora Hospital to return that Medical Device to you and to provide that Te Whatu Ora Hospital with a refund for that Medical Device.
- (c) This clause confers a benefit on (and is enforceable by) Te Whatu Ora Hospitals in accordance with the Contract and Commercial Law Act 2017, Part 2, Subpart 1.

9.7 Safety Data Sheets

You must make available to each Te Whatu Ora Hospital, in English, a current Safety Data Sheet relevant to any products being supplied under this Agreement that are intended to be used with a Medical Device (for example, cleaning or disinfecting chemicals or substances for use with the Medical Device) that are not Medical Devices in and of themselves, the first time that Medical Device is supplied to the Te Whatu Ora Hospital and thereafter you must provide an updated Safety Data Sheet that relates to any such products being supplied under this Agreement in relation to a Medical Device to any Te Whatu Ora Hospital that you

have supplied such Medical Device to in the past 12 (twelve) months and thereafter, the next time such Medical Device is supplied to that Te Whatu Ora Hospital.

9.8 Training and Education about Medical Devices

- (a) You will provide, at no cost to the Te Whatu Ora Hospitals, at a time or times agreed between you and the relevant Te Whatu Ora Hospital, to the extent applicable to the Medical Device, the training and education services (which shall include but not be limited to training courses, education courses or in-service as the context requires) in accordance with the provisions of this Agreement (including Part 8 and/or Part 9), which will include:
- (i) comprehensive initial and follow-up training and education on the benefits and efficient use of the Medical Devices (or operator training, as applicable), which will be conducted on site at the Te Whatu Ora Hospital's premises or as otherwise set out in Part 8 and/or Part 9;
 - (ii) training in the maintenance of the Medical Device(s) at the Medical Device manufacturer's on-site or country of origin training facilities; or
 - (iii) training in the maintenance of the Medical Device(s) on site at the Te Whatu Ora Hospital's premises or other agreed location equivalent to that provided at the Medical Device(s) manufacturer's on-site or country of origin training facilities,
- and such other services as are detailed in Part 8 and/or Part 9 of this Agreement.
- (b) Each Te Whatu Ora Hospital, acting reasonably, will have the right to nominate which of its Personnel attend any training and education service and shall have the right to vary the number of persons who are required to attend any training and education service conducted by you.
- (c) A Te Whatu Ora Hospital may postpone the provision of training and education services scheduled to be provided on 48 hours' notice to you, in which case you will reschedule the training and education services to occur as soon as reasonably practicable and at a time agreed by the Te Whatu Ora Hospital.
- (d) The training and education services shall be of a standard acceptable to the relevant Te Whatu Ora Hospital (acting reasonably) such that they provide to the Te Whatu Ora Hospital's Personnel who attend the training and education services:
- (i) sufficient theoretical and practical knowledge and understanding of the relevant Medical Devices, their design, operation and maintenance requirements; and
 - (ii) a level of proficiency in the application of that knowledge and understanding, to enable them, in turn, to be competent to train others in the use and maintenance of the Medical Devices.
- (e) You warrant that you have and will exercise the requisite skill, judgement, ability, capacity and experience expected of a professional experienced in the provision of training and education services and as is necessary to provide the training and education services in accordance with the terms of this Agreement. Te Whatu Ora Hospitals shall be entitled to conduct a verification of the qualifications and experience of your Personnel providing training and education services.
- (f) In undertaking and providing any training and education services provided under clauses 9.8 and 9.9, you will co-operate with the relevant Te Whatu Ora Hospital and other contractors (if any) engaged by the Te Whatu Ora Hospital in relation to the training and education services. You agree to act in good faith and fully co-operate

with these parties to support the effective implementation of the training and education services in respect of the relevant Medical Devices.

- (g) You will report to the relevant Te Whatu Ora Hospital's representative on training and education provision matters as reasonably required.
- (h) You will provide all the resources necessary to provide the training and education services under this Agreement.
- (i) A Te Whatu Ora Hospital, acting reasonably, may direct you to cease the engagement of any of your Personnel involved in the provision of the training and education services at the Te Whatu Ora Hospital or to stipulate that the training and education services will be provided by a specific member of your Personnel. Where the relevant Te Whatu Ora Hospital has specified a specific member of your Personnel it is a fundamental term that the specified member of your Personnel provides the training and education services.
- (j) Without limiting any other remedies available to the Te Whatu Ora Hospital to whom you are providing training and education services, provided under clauses 9.8 and 9.9, you will remedy any defects associated with those services at no extra cost to the relevant Te Whatu Ora Hospital.
- (k) Upon the completion of the training and education services you will leave the relevant Te Whatu Ora Hospital's sites in a clean and tidy state for use and occupation by the Te Whatu Ora Hospital.
- (l) You must return all property, used for the provision of training and education services, belonging to the relevant Te Whatu Ora Hospital in a satisfactory condition and co-operate and hand to the relevant Te Whatu Ora Hospital all copies of files, documents, data and information held by you.

9.9 Training and education materials

- (a) You will provide each Te Whatu Ora Hospital with:
 - (i) brochures and clinical aids to support the Te Whatu Ora Hospital in identifying the Medical Device that will best meet its requirements, including evaluations in regard to Medical Device suitability and clinical acceptability;
 - (ii) materials and teaching and training aids as may be necessary to enable the Te Whatu Ora Hospital itself to undertake the provision of training services as specified in clause 9.8(d)(ii); and
 - (iii) such specific information as may be required by the Te Whatu Ora Hospital in relation to a Medical Device and as stated in Part 8 and/or Part 9.
- (b) You will regularly review your training and education materials and incorporate new material and provide this to Te Whatu Ora Hospitals where appropriate.

9.10 Costs associated with training and education

The cost of providing the training and education services and the associated training and education materials, will be met by you, which includes:

- (a) all course and in-servicing fees and associated training and education resource expenses;

- (b) airfares and on location costs (including local travel expenses to and from the course venue, accommodation and living expenses) in respect of your Personnel; and
- (c) where applicable and mutually agreed with a Te Whatu Ora Hospital, airfares and on location costs (including local travel expenses to and from the course venue, accommodation and reasonable living expenses) in respect of Te Whatu Ora Hospital(s) Personnel in relation to all training and education.

10. Special obligations

- (a) Part 8 and/or Part 9 sets out any additional obligations that are specific to a Category of Medical Device.
- (b) Part 8 and/or Part 9 sets out any additional obligations that are specific to a specific Medical Device.

11. Quality standards applying to listed Medical Devices

Part 8 and/or Part 9 sets out any quality standards that apply to a specific Medical Device and any relevant Category of Medical Device that you supply pursuant to this Agreement.

12. Performance Standards

Schedule 3 sets out the Performance Standards and performance regime that will be used by Pharmac to assess your performance under this Agreement.

13. Medical Devices updates and upgrades

13.1 Medical Devices Updates

- (a) You are not permitted to supply updated or modified Medical Devices to Te Whatu Ora Hospitals without first notifying Pharmac and without Pharmac's express written consent. Provided that the updated or modified Medical Device continues to conform to the relevant Product Specification for that Medical Device, such consent will not be unreasonably withheld. Where Pharmac's express written consent has been obtained, any such updated Medical Device will then be deemed to be the same product as the Medical Device that it is updating such that the Price and all other terms that applied to the Medical Device in its original form will apply to the updated Medical Device.
- (b) In the event that you make updates or modifications to a Medical Device which in Pharmac's opinion cause that Medical Device to be different in nature (either clinically or otherwise) to the nature of the original Medical Device as at the date of this Agreement, Pharmac may give notice to you that you may not supply that Medical Device in its updated form in place of the Medical Device in its original form pursuant to this Agreement until Pharmac has given its approval for you to do so.
- (c) If Pharmac gives notice under (b) and then subsequently determines that it cannot give approval under (b), Pharmac may, in the event that you are unable to supply the Medical Device in its original form, delist the Medical Device from Section H, Part III of the Pharmaceutical Schedule.
- (d) If a Medical Device uses computer software, you must provide updates for that computer software and subsequent modifications and software for fault diagnosis at

your expense to any Te Whatu Ora Hospital that has procured the relevant Medical Device.

13.2 **Medical Devices upgrades**

- (a) As clinical practice evolves or as new technology becomes available, end users may alter their clinical practice. This could result in Te Whatu Ora Hospitals ceasing to use any or all of the Medical Devices covered by this Agreement or expressing a preference to use an upgraded form of a Medical Device. In the event that Te Whatu Ora Hospitals cease to use any of the Medical Devices covered by this Agreement or express a preference to use an upgraded form of a Medical Device, Pharmac reserves the right to delist that Medical Device from Section H, Part III of the Pharmaceutical Schedule (thereby removing that Medical Device from being covered by this Agreement) without affecting any other provision in this Agreement or the listing of any other Medical Device.
- (b) In addition to or as an alternative to Pharmac's right under (a) to delist the original Medical Device, Pharmac may choose to list the upgraded form of that Medical Device as a substitute medical device in Section H, Part III of the Pharmaceutical Schedule at the same price as the original Medical Device that is being substituted or at a price mutually agreed between us, in which case that substitute medical device will become a Medical Device covered by this Agreement and will be supplied by you on the same terms as the original Medical Device that it is substituting (subject to any alternative agreement reached between the parties).
- (c) In the event that Pharmac does not delist a Medical Device under (a) but also chooses to list an upgraded substitute Medical Device under (b), Pharmac may reduce the price that the original Medical Device is listed at following consultation with you which may be to a set percentage lower or to a price agreed between the parties.
- (d) You are required to keep Pharmac informed of any international trends and studies that are relevant to or relate in any way to any Medical Devices by supplying Pharmac with relevant information about those international trends and studies, including by providing journal or other published articles.

PART 3: Ordering and delivering Medical Devices

14. Purchase Orders

- (a) This clause 14 applies to all Medical Devices other than Consignment Medical Devices.
- (b) All orders for Medical Devices must be placed through a valid Purchase Order before you may supply Medical Devices to the Te Whatu Ora Hospital or Logistics Provider (as applicable).
- (c) A valid Purchase Order under (b) is one that is issued in any one of the following ways:
 - (i) the relevant Te Whatu Ora Hospital or Logistics Provider submits a request in writing via email or facsimile either in the Te Whatu Ora Hospital's, Logistics Provider's or your standard Purchase Order form, or through some other written format;
 - (ii) the relevant Te Whatu Ora Hospital or Logistics Provider places an order over the phone with you, which you capture in writing in the Te Whatu Ora Hospital's, Logistics Provider's or your standard Purchase Order form, or through some other written format and send to the Te Whatu Ora Hospital or Logistics Provider for confirmation prior to supply;
 - (iii) the relevant Te Whatu Ora Hospital or Logistics Provider submits a Purchase Order through a centralised electronic purchasing system; and
 - (iv) any other method approved by Pharmac.

For the avoidance of doubt, you shall have an auditable system for tracking receipt of Purchase Orders and shall provide a report upon request from Pharmac of Purchase Orders received from a Te Whatu Ora Hospital or Logistics Provider in accordance with clause 24 of this Agreement.

- (d) All Purchase Orders under (b) must, as a minimum:
 - (i) include a Te Whatu Ora Hospital or Logistics Provider Purchase Order number;
 - (ii) clearly specify the Medical Device(s) being procured and the quantities; and
 - (iii) set out the Price of the Medical Device(s) being procured, being the Price(s) as listed or referenced in Schedule 1, both itemised for each Medical Device and with a total for all Medical Devices being procured.
- (e) The applicable Purchase Order number must be quoted on all related packing slips and invoices.
- (f) The relevant Te Whatu Ora Hospital or Logistics Provider (as applicable) will not be required to pay for any Medical Devices delivered to the Te Whatu Ora Hospital or Logistics Provider (if applicable), if those Medical Devices were supplied by you other than pursuant to a valid Purchase Order.

- (g) If a Te Whatu Ora Hospital or Logistics Provider returns Medical Devices to you in circumstances where Medical Devices were supplied by you other than pursuant to a valid Purchase Order, you are required to pay the Te Whatu Ora Hospital's or Logistics Provider's reasonable costs of returning the Medical Devices to you (along with any costs that the Te Whatu Ora Hospital or Logistics Provider incurs in respect of collecting the Medical Devices to return to you, if applicable) upon receiving written notice from the Te Whatu Ora Hospital or the Logistics Provider of the costs incurred.

15. Consignment stock

- (a) You may supply Consignment Medical Devices to Te Whatu Ora Hospitals on the following terms:
 - (i) you may only supply a Consignment Medical Device to a Te Whatu Ora Hospital with the written approval of the Te Whatu Ora Hospital and, where Pharmac gives notice to you that its approval is also required to supply a Consignment Medical Device to a Te Whatu Ora Hospital, of Pharmac;
 - (ii) you may only place such quantities of Consignment Medical Devices in a Te Whatu Ora Hospital on consignment up to the limits agreed with the Te Whatu Ora Hospital for each Medical Device. Pharmac may at any time require such limits to be reduced by giving written notice to the relevant Te Whatu Ora Hospital and to you, following consultation with the relevant Te Whatu Ora Hospital;
 - (iii) for each separate Te Whatu Ora Hospital you must retain a record of:
 - (A) the total number of each Consignment Medical Device you have placed at that Te Whatu Ora Hospital and which have not been used by the Te Whatu Ora Hospital at any one time;
 - (B) the number of each Consignment Medical Device you replenish at the Te Whatu Ora Hospital;
 - (C) the dates that you replenish each Consignment Medical Device in (B),and you must make this information immediately available to the relevant Te Whatu Ora Hospital and to Pharmac upon a request being made by the Te Whatu Ora Hospital or Pharmac;
 - (iv) ownership of and associated risk in Consignment Medical Devices remains with you until such time as the Consignment Medical Device is used by the Te Whatu Ora Hospital in which case delivery of that Consignment Medical Device will be deemed to have occurred and risk and unencumbered title will pass to the Te Whatu Ora Hospital at the point of use by the Te Whatu Ora Hospital;
 - (v) expired Consignment Medical Devices will be replaced by you with no charge to the Te Whatu Ora Hospital;
 - (vi) you will notify the Te Whatu Ora Hospital of any damaged Consignment Medical Devices or Consignment Medical Devices out of their original packaging. The Te Whatu Ora Hospital's liability (if any) for such Consignment Medical Devices will be determined on a case-by-case basis should you seek payment from the Te Whatu Ora Hospital;
 - (vii) you must comply with any rules specified in the Pharmaceutical Schedule that relate to Consignment Medical Devices;

- (viii) delivery of Consignment Medical Devices will be performed to cause the least possible disruption to the Te Whatu Ora Hospital and must only occur on such dates and times and frequencies and to such locations as the Te Whatu Ora Hospital agrees. The Te Whatu Ora Hospital may request that you postpone a planned delivery of Consignment Medical Devices until a later date that is convenient for the Te Whatu Ora Hospital; and
 - (ix) any invoice relating to Consignment Medical Devices must clearly specify that the invoice relates to Consignment Medical Devices and payment will be made on the terms set out in clause 23 of this Agreement.
- (b) Pharmac may, at any time, conduct an audit into your practices relating to delivering and replenishing Consignment Medical Devices to any or all Te Whatu Ora Hospitals. You agree to co-operate to the fullest extent with any request made by Pharmac in relation to such an audit, including by making your staff or contractors available to discuss your practices and by providing information requested by Pharmac.
 - (c) You must complete a stock-take, once every six months, of Consignment Medical Devices held by each Te Whatu Ora Hospital (at times to be agreed with each Te Whatu Ora Hospital). The results of the stock-take must be provided to the Te Whatu Ora Hospital and to Pharmac in an excel spreadsheet within one week of the stock-take being completed.
 - (d) All Consignment Medical Devices shall remain in their original packaging configuration until opened for clinical use.
 - (e) As soon as practicable following receipt of the Consignment Medical Devices, the Te Whatu Ora Hospital shall inspect the Consignment Medical Devices and report any failure to comply with the inspection criteria stated in paragraphs (i) to (iii) below. The Te Whatu Ora Hospital may not open the external packaging of the Consignment Medical Devices as part of its inspection. Inspection criteria, for the purpose of this clause (e) shall comprise the following:
 - (i) a check that there is no damage to exterior packaging;
 - (ii) a check that product code, product description and quantities received match the consignment note;
 - (iii) a check that quality assurance tags (where a quality assurance tag is required), which are visible on the outer packaging of the Consignment Medical Devices, do not indicate an out-of-specification event.

In the event that a Consignment Medical Device does not comply with one or more of the inspection criteria stated in paragraphs (i) to (iii) above, you shall replace the relevant Consignment Medical Device with an Alternative Medical Device at no additional charge.

- (f) The Te Whatu Ora Hospital shall ensure that the exterior packaging of the Consignment Medical Devices is not written on or marked in any manner by Te Whatu Ora Hospital Personnel.
- (g) The Te Whatu Ora Hospital shall store Consignment Medical Devices at a location ("**Storage Area**") which is agreed between the Te Whatu Ora Hospital and you.
- (h) The Te Whatu Ora Hospital Storage Area shall meet the environmental storage conditions specified in the manufacturer's instructions for that Consignment Medical Device (where those instructions have been notified to the Te Whatu Ora Hospital).

- (i) The Te Whatu Ora Hospital shall only allow properly trained Personnel to handle the Consignment Medical Devices, with such training to be facilitated by you, at no cost to the Te Whatu Ora Hospital, as and where required.
- (j) The Te Whatu Ora Hospital's use of Consignment Medical Devices shall be on a first-expiry, first-out stock management basis to ensure stock rotation and reduce risk of stock loss through expiry.
- (k) The Te Whatu Ora Hospital shall maintain the traceability of all Consignment Medical Devices used.
- (l) In the event that:
 - (i) a Consignment Medical Device has been removed from its original packaging configuration by Te Whatu Ora Hospital Personnel prior to being opened for clinical use;
 - (ii) the exterior packaging of a Consignment Medical Device has been written on or marked in any manner by Te Whatu Ora Hospital Personnel prior to being opened for clinical use; or
 - (iii) a Consignment Medical Device has been stored outside the environmental storage conditions specified in the manufacturer's instructions (where those instructions have been notified to the Te Whatu Ora Hospital) by Te Whatu Ora Hospital Personnel,

then the Te Whatu Ora Hospital shall be deemed to have taken ownership of, and the Te Whatu Ora Hospital shall be liable to pay for, that Consignment Medical Device.

- (m) You may, with the prior approval of a Te Whatu Ora Hospital, add or remove Consignment Medical Devices from the Te Whatu Ora Hospital's consignment inventory upon one (1) business days' notice. For each stock transfer, you must notify the Te Whatu Ora Hospital in writing and maintain a record of:
 - (i) the total number of each Consignment Medical Device you have removed or added; and
 - (ii) the individual serial number(s) of each Consignment Medical Device you have removed or added.

16. Delivery

- (a) This clause 16 applies to all Medical Devices other than Consignment Medical Devices unless otherwise specified in Part 8 and/or Part 9.
- (b) The Medical Devices will be delivered to the Te Whatu Ora Hospital or Logistics Provider (as applicable), as noted on the Purchase Order, on such days, at such times, to such places and in such quantities as required by the Te Whatu Ora Hospital or the Logistics Provider (as applicable). A delivery note, in accordance with the Te Whatu Ora Hospital's or Logistics Provider's requirements, stating the Te Whatu Ora Hospital's or Logistics Provider's Purchase Order number(s) and itemising each Medical Device procured (including the product reference number as listed or referenced in Schedule 1 next to the applicable Medical Device) and the quantity delivered will be furnished with each supply.
- (c) Medical Devices must be delivered within:

- (i) three (3) business days of a Purchase Order having been received by you where delivery is to a Logistics Provider;
- (ii) three (3) business days of a Purchase Order having been received by you where delivery is to a Te Whatu Ora Hospital; or
- (iii) such other period of time as may be specified in Part 8 and/or Part 9 in respect of a particular Medical Device.

For the purposes of calculating the period of time for a delivery under this paragraph (c), a business day includes a Saturday. Notwithstanding the preceding sentence, in the event a delivery of a Medical Device falls due for delivery on a Saturday, the delivery will only occur on the Saturday if there are courier delivery operators operating in the place of delivery on a Saturday morning and the Te Whatu Ora Hospital or Logistics Provider (as applicable) had indicated on the Purchase Order that a Saturday delivery is required and that Saturday is not a statutory public holiday in New Zealand.

- (d) A Te Whatu Ora Hospital or Logistics Provider may request an urgent delivery of a Medical Device, which must be delivered:
 - (i) by 9.00am on the business day following the day on which a Purchase Order has been received by you where an urgent delivery request is made and received by you by 3.00pm;
 - (ii) within 24 hours on the business day following the day on which a Purchase Order has been received by you where an urgent delivery request is made and received by you after 3.00pm; or
 - (iii) within such other period of time as may be specified in Part 8 and/or Part 9 in respect of a particular Medical Device.

For the purposes of calculating the period of time for a delivery under paragraph (d), a business day includes a Saturday. Notwithstanding the preceding sentence, in the event a delivery of a Medical Device falls due for delivery on a Saturday, the delivery must only occur on the Saturday if there are courier delivery operators operating in the place of delivery on a Saturday morning and the Te Whatu Ora Hospital or Logistics Provider (as applicable) had indicated on the Purchase Order that a Saturday delivery is required and that Saturday is not a statutory public holiday in New Zealand.

- (e) Notwithstanding clause 21.1(c), if an urgent delivery request is made in accordance with (d) and delivery occurs within the timeframes specified in (d), you may charge the Te Whatu Ora Hospital or Logistics Provider a reasonable urgent delivery fee, provided this has been notified to the Te Whatu Ora Hospital or Logistics Provider in advance and does not exceed \$50 per Purchase Order. In accordance with clause 21.1(c), you shall not otherwise apply any premium or seek to claim any additional costs or expenses in connection with or related to any special hours or days of work or for any other reason.
- (f) Delivery of the Medical Devices will be performed to cause the least possible disruption to the Te Whatu Ora Hospital or Logistics Provider (as applicable).
- (g) The Te Whatu Ora Hospital or Logistics Provider (as applicable) may postpone or cancel any delivery within 24 hours of your receipt of a Purchase Order by giving notice to you, unless the Medical Device(s) have already been shipped, and you will reschedule the postponed delivery to occur as soon as reasonably practicable, or cancel the delivery (at no cost to the Te Whatu Ora Hospital), as applicable.

- (h) The Te Whatu Ora Hospital or Logistics Provider (as applicable) may amend any Purchase Order (by increasing or decreasing the quantity of Medical Devices ordered or by adding new Medical Devices to the order) within 24 hours of a Purchase Order having been received by you, by giving notice to you, unless the Medical Device(s) have already been shipped. The timeframes for delivery that related to the original Purchase Order will remain unless otherwise agreed with the Te Whatu Ora Hospital, but in any event may not increase by more than one business day. Any amended Purchase Orders must be recorded in the same way as original Purchase Orders, as described in clause 14.

- (i) A Te Whatu Ora Hospital or Logistics Provider (as applicable) may amend any Purchase Order (by increasing the quantity of Medical Devices ordered or by adding new Medical Devices to the order) at any time prior to delivery of the Medical Devices, even if the Medical Device(s) the subject of the original Purchase Order have already been shipped by you, in which case the following will apply:
 - (i) the timeframes for the delivery of any additional Medical Device(s) added through the amendment of the Purchase Order in accordance with this paragraph (i) will begin from the date the amended Purchase Order is received by you but the timeframes for delivery of the Medical Device(s) originally ordered through the Purchase Order will remain as they would have been had the Purchase Order not been amended;
 - (ii) when the additional Medical Device(s) are delivered, the delivery slip must clearly identify the Purchase Order under which the additional Medical Device(s) were ordered, and should also note that other Medical Devices with the same Purchase Order number have previously been shipped or delivered (as applicable);
 - (iii) any Purchase Orders amended pursuant to this paragraph (i) must be recorded in the same way as original Purchase Orders, as described in clause 14; and
 - (iv) the partial delivery provisions in paragraphs (j) and (k) below will not apply to the Purchase Order unless any of the Medical Device(s) originally ordered have already been placed on backorder or the additional Medical Devices ordered in accordance with this paragraph (i) are not immediately available and may need to be placed on backorder (with the agreement of the Te Whatu Ora Hospital or Logistics Provider (as applicable)).

- (j) Partial deliveries of Medical Devices ordered may only be made, and the remaining Medical Devices ordered placed on backorder, after contacting the relevant Te Whatu Ora Hospital or Logistics Provider (as applicable) as named on the Purchase Order and obtaining their prior agreement to any partial delivery of a Purchase Order and placement of the remaining Medical Devices in that Purchase Order on backorder.

- (k) Where a partial delivery of Medical Devices occurs in accordance with (j), the remaining Medical Devices stated in the Purchase Order that will not be delivered within the timeframes specified in (c) or (d), as applicable, must be placed on backorder unless otherwise specified by the Te Whatu Ora Hospital or Logistics Provider. If a Te Whatu Ora Hospital or Logistics Provider agrees to a partial delivery of Medical Devices in a Purchase Order and Medical Devices are placed on backorder, you must notify the Te Whatu Ora Hospital or Logistics Provider at the point when the relevant Purchase Order is received by you, when the backordered Medical Devices will be delivered. Any partial delivery of a Purchase Order or delivery of Medical Devices on backorder must be accompanied by a delivery note that explains either, as applicable:
 - (i) which remaining Medical Devices in a Purchase Order, not included in the delivery, have been placed on backorder; or

- (ii) that the Medical Devices in the delivery were placed on backorder and the Purchase Order number that they were ordered through.
- (l) You will package the Medical Devices in an appropriate manner having regard to the type of the Medical Devices and the transportation used. In the event the Te Whatu Ora Hospital or Logistics Provider (as applicable) has notified you that it requires notice of any change to packaging, any intention to change the packaging of the Medical Devices must then be notified to the Te Whatu Ora Hospital or Logistics Provider (as applicable) in advance and the Te Whatu Ora Hospital's or Logistics Provider's prior agreement obtained, such agreement not to be unreasonably withheld, before any change is made.
- (m) Risk and unencumbered title in the Medical Devices will pass to the Te Whatu Ora Hospital or Logistics Provider (as applicable) upon signing of the delivery note furnished with the Medical Devices. However, receipt of or signature on a delivery note will not be taken as acceptance of either the quality or quantity of the Medical Devices. Acceptance by the Te Whatu Ora Hospital or Logistics Provider (as applicable) will be subject to subsequent inspection and/or use of the Medical Devices.
- (n) Any special delivery requirements in respect of a particular Medical Device are as set out in Part 8 and/or Part 9 and apply in place of any of the requirements in this clause 16, to the extent that there is any conflict or inconsistency between the provisions.

17. Information to be provided and related requirements for Medical Devices that are delivered

You will ensure that each Medical Device supplied is labelled with the following information:

- (a) all sterile Medical Devices, non-sterile Medical Devices, packs and sets will be clearly labelled and note the:
 - (i) name of the manufacturer of the Medical Device and/or the name of the manufacturer's distributor in New Zealand;
 - (ii) product reference/vendor part no.;
 - (iii) unique lot/batch no.;
 - (iv) manufacturing date (if applicable);
 - (v) expiry date;
 - (vi) any other information reasonably requested by the Te Whatu Ora Hospital or Logistics Provider;
- (b) sterile Medical Devices, packs and sets will note the method of sterilisation;
- (c) sterile Medical Devices will be packaged in a form that is suitable for the particular Medical Device; and
- (d) packs and sets will list all components.

18. No obligation to procure minimum quantity

- (a) Nothing in this Agreement will prevent any Te Whatu Ora Hospital or Logistics Provider procuring medical devices similar to, or the same as, the Medical Devices from any other party. Pharmac does not guarantee any specific volume of business from Te Whatu Ora Hospitals or Logistics Providers under this Agreement. All information provided by Pharmac or any Te Whatu Ora Hospital or Logistics Provider is only an estimate and you confirm that you will not rely on these estimates.
- (b) The minimum order quantity for a Medical Device shall be the supplier unit of measure per item, as listed or referenced in Schedule 1. Subject to the minimum order quantity stated in the preceding sentence of this paragraph (b), there is no other obligation in this Agreement which requires a Te Whatu Ora Hospital or Logistics Provider to order a minimum quantity or value of a Medical Device or Medical Devices in any single Purchase Order or allows you to charge a Te Whatu Ora Hospital or Logistics Provider an order fee or premium for ordering a minimum quantity or value unless specified in Part 8 and/or Part 9.
- (c) You may only charge the Te Whatu Ora Hospital or Logistics Provider a minimum order charge (including any additional delivery fee) if this is expressly set out in Part 8 and/or Part 9 in respect of the particular Medical Device or Medical Devices. If no relevant minimum order charge or additional delivery fee is set out in Part 8 and/or Part 9, the minimum order charge shall be the Price of the Medical Devices ordered without any additional charges or additional delivery fees being applied to that order.

19. Return of stock

- (a) You agree that a Te Whatu Ora Hospital or Logistics Provider (as applicable) may return (at the Te Whatu Ora Hospital's or Logistics Provider's cost) any quantity of Medical Devices, provided the Te Whatu Ora Hospital or Logistics Provider (as applicable) notifies you in writing within five (5) business days of the date of delivery of those Medical Devices of its intention to return the Medical Devices and that the returned Medical Devices are in a resalable condition (where they were delivered in such a condition).
- (b) In the event that the Te Whatu Ora Hospital or Logistics Provider gives notice under (a), the Medical Devices must either be returned by the Te Whatu Ora Hospital or Logistics Provider to you or arrangements must have been made with you for you to collect the Medical Devices from the Te Whatu Ora Hospital or Logistics Provider, within ten (10) business days of the date of delivery of those Medical Devices.
- (c) In the event that the Te Whatu Ora Hospital or Logistics Provider gives notice under (a) that it wishes to return Medical Devices to you and returns the Medical Devices in accordance with (b), you agree to either:
 - (i) not invoice the Te Whatu Ora Hospital or Logistics Provider for those Medical Devices in the event that an invoice has not yet been generated in respect of those Medical Devices;
 - (ii) cancel the invoice (or issue a replacement invoice, if applicable), if an invoice has already been sent to the Te Whatu Ora Hospital or Logistics Provider but that invoice has not yet been paid; or
 - (iii) provide a refund for the Price of those returned Medical Devices if a Te Whatu Ora Hospital or Logistics Provider has already paid for the Medical Devices that it wishes to return.

- (d) Notwithstanding (c), where a Te Whatu Ora Hospital or Logistics Provider returns any Medical Devices pursuant to (a), you may invoice the Te Whatu Ora Hospital or Logistics Provider for any actual and reasonable administration and original delivery costs (along with any costs that you incur in respect of collecting the Medical Devices from the Te Whatu Ora Hospital or Logistics Provider, if applicable), provided that such costs do not exceed \$100 for the relevant Medical Devices. For the avoidance of doubt the cap referred to in this clause is a total cap for a return and shall not be increased by the multiplication of identical Medical Device units which comprise any return.
- (e) You are required to take steps to mitigate the cost of any administration or delivery costs that you may charge under (d). Such steps may include reallocating the Medical Devices to another Te Whatu Ora Hospital or Logistics Provider (or helping to facilitate this for the Te Whatu Ora Hospital or Logistics Provider), or collecting the Medical Devices at the same time as you are already making a delivery.
- (f) Other than the costs you are permitted to charge a Te Whatu Ora Hospital or Logistics Provider under (d), unless otherwise agreed to by Pharmac in writing, you must not charge a Te Whatu Ora Hospital or Logistics Provider any additional fees in relation to the return of Medical Devices.

20. Te Whatu Ora Hospital or Logistics Provider sites

20.1 General

- (a) In performing your obligations under this Agreement you shall comply with any Te Whatu Ora Hospital policies, which have been notified to you.
- (b) You acknowledge that:
 - (i) a Te Whatu Ora Hospital or Logistics Provider may relocate and re-organise hospital and/or health services across their hospital and/or service delivery sites from time to time, which may include demolition, building, re-development, refurbishment and upgrade works in relation to existing and new buildings and service areas ("**Works**"); and
 - (ii) you will demonstrate tolerance to such Works and will continue to provide the Medical Devices (and any related services described in this Agreement) notwithstanding the Works and any damage caused by you to any Te Whatu Ora Hospital's site or to any Te Whatu Ora Hospital's property or to any person lawfully on any Te Whatu Ora Hospital's sites will be made good by you at your expense.
- (c) You will respect the privacy of patients of Te Whatu Ora Hospitals at all times and at no time shall you or your Personnel discuss or in any way disclose any information concerning the condition or medical history of any past or present patient of a Te Whatu Ora Hospital or otherwise disclose any matter concerning patient confidentiality that you become aware of in the course of supplying Medical Devices under this Agreement.

20.2 Health and safety

- (a) Where delivery of the Medical Devices (or provision of any related services described in this Agreement) occurs within the Te Whatu Ora Hospital's or Logistics Provider's facilities, your Personnel will observe all relevant health and safety requirements, any statutory requirements, and any code of conduct provided to you by the Te Whatu Ora Hospital or Logistics Provider.

- (b) You will comply with all applicable statutes, regulations and other subordinate legislation in force, or that comes into force, in New Zealand while this Agreement remains current in respect of health and safety in employment (including the Health and Safety at Work Act 2015 and all regulations made under that Act).
- (c) Where you and Te Whatu Ora, Logistics Providers or Pharmac have duties in relation to the same matter imposed by the Health and Safety at Work Act 2015, you must consult, coordinate and cooperate with Te Whatu Ora , Logistics Providers and Pharmac to ensure compliance with those duties.
- (d) You must inform Pharmac and Te Whatu Ora or Logistics Provider of any Notifiable Event (as defined in the Health and Safety at Work Act 2015) that occurs in connection with you carrying out your obligations under this Agreement.
- (e) You will report to Pharmac on matters relating to health and safety in connection with you carrying out your obligations under this Agreement. You must report in writing or otherwise in a form to be prescribed by and at times required by Pharmac.

20.3 Notification of breach

You must notify the Te Whatu Ora Hospital or Logistics Provider immediately if you become aware that you or your Personnel are or may be in breach or are likely to be in breach of clause 20.1 or clause 20.2 and the Te Whatu Ora Hospital or Logistics Provider may deny access to any Te Whatu Ora Hospital's site to any of your Personnel who do not comply with the requirements of this clause.

PART 4: Price and Payment

21. Price

21.1 Supply price

- (a) The Price at which each Medical Device is supplied by you must not exceed the Price as listed or referenced in Schedule 1 or the price listed in Section H, Part III of the Pharmaceutical Schedule (if this is less due to the application of relevant provisions in this Agreement).
- (b) The Te Whatu Ora Hospital or Logistics Provider (as applicable) will pay you the Price as listed or referenced in Schedule 1 for that Medical Device plus GST (if any) for provision of the Medical Device, in accordance with the terms set out in this Part 4.
- (c) The Price(s) for the Medical Devices are capped under this Agreement at the prices listed or referenced in Schedule 1. You shall not apply any premium or seek to claim any additional costs or expenses (including delivery costs) in connection with or related to those Prices for any special hours or days of work or for any other reason unless expressly specified in Part 8 and/or Part 9.
- (d) The Price(s) for the Medical Devices include all charges for import, duty, freight, packing, transportation, insurance and all other charges applied to the landing and delivery of the Medical Devices and all associated works and services and all costs incurred by you to fully and effectively supply the Medical Devices to the Te Whatu Ora Hospital or Logistics Provider (as applicable), including costs associated with unpacking, assembly, installation and commissioning of any Medical Devices, all of which will be arranged by you and be your responsibility. If a Te Whatu Ora Hospital or a Logistics Provider (as applicable) is or becomes liable for any import (or export) duty or charge in connection with the import of any Medical Device into New Zealand you shall promptly reimburse the Te Whatu Ora Hospital or a Logistics Provider for that amount (plus GST if any). You will provide all management, administration and supervisory Personnel, labour materials, equipment and anything else required to provide the Medical Devices in accordance with this Agreement.
- (e) A Te Whatu Ora Hospital or Logistics Provider (as applicable) may deduct any withholding tax required to be deducted from any payments and forward that withholding tax to the Inland Revenue. The net amounts paid after deduction of any withholding tax shall be a complete and final discharge of a Te Whatu Ora Hospital's or Logistics Provider's (as applicable) obligation to make the relevant payment and the Te Whatu Ora Hospital or Logistics Provider shall not be under any liability to gross up or otherwise compensate you for the amount of that withholding.
- (f) You must notify each Te Whatu Ora Hospital's and, if applicable, each Logistics Provider's Chief Financial Officer, and Pharmac, if you are a non-resident for New Zealand tax purposes and of any change in your residence status for New Zealand tax purposes (and you must promptly upon request from such entity or person provide a copy of any certificate of exemption for non-resident contractor's withholding tax, if applicable). If Inland Revenue imposes withholding taxes and penalties (including interest) on a Te Whatu Ora Hospital or, if applicable, a Logistics Provider in connection with any payment by that Te Whatu Ora Hospital or Logistics Provider (as applicable) to you, then that Te Whatu Ora Hospital or Logistics Provider will invoice

you for payments made to the Inland Revenue and these will be reclaimable as a debt due to that Te Whatu Ora Hospital or Logistics Provider, as applicable.

- (g) Any costs relating to training and education services provided under clause 9.8 and 9.9 will be met by you in accordance with clause 9.10 subject to any special payment terms that may be specified in Part 8 and/or Part 9.
- (h) Notwithstanding the provisions contained in this clause 21.1, you and Pharmac may by mutual agreement adjust the Price of each Medical Device listed or referenced in Schedule 1 of this Agreement. Any new prices shall be agreed in writing and shall apply from the date agreed between the parties.

21.2 Price adjustment if one Te Whatu Ora Hospital is to be offered a lower price

Notwithstanding clause 9.1(b), you may supply a Medical Device to a Te Whatu Ora Hospital or a Logistics Provider at a Price that is less than the price listed or referenced in Schedule 1 provided that you obtain Pharmac's prior written agreement, and that you:

- (a) notify Pharmac, every Te Whatu Ora Hospital, and every Logistics Provider of the reduced Price of the Medical Device;
- (b) notify Pharmac, every Te Whatu Ora Hospital, and every Logistics Provider of the period of time for which the Price will be reduced below the price listed or referenced in Schedule 1;
- (c) supply, and make available for supply, the Medical Device to every Te Whatu Ora Hospital and every Logistics Provider at the reduced Price for the period notified pursuant to (b); and
- (d) in the event that the reduction in the price is to be a permanent reduction, notify Pharmac in writing accordingly, in which case Pharmac may:
 - (i) vary the Price of the relevant Medical Device as listed or referenced in Schedule 1, effective from the date of such notification; and
 - (ii) at intervals that are convenient to Pharmac, update the price listed in Section H, Part III of the Pharmaceutical Schedule,

to reflect the reduced Price.

22. Invoicing

22.1 Te Whatu Ora Hospital placing the Purchase Order

- (a) Where a Purchase Order has been received from a Te Whatu Ora Hospital or where a Te Whatu Ora Hospital has used a Consignment Medical Device you are to invoice the particular Te Whatu Ora Hospital at the end of each month, but no later than the second business day following the month to which the invoice in respect of the Medical Device relates, specifying for the Medical Devices supplied during that month:
 - (i) your delivery note reference number (also required for Consignment Medical Devices unless otherwise agreed with the individual Te Whatu Ora Hospital);
 - (ii) the particular Te Whatu Ora Hospital's Purchase Order reference number (also required for Consignment Medical Devices unless otherwise agreed with the individual Te Whatu Ora Hospital);

- (iii) the net amount payable in respect of the Medical Device supplied to that Te Whatu Ora Hospital in accordance with this Agreement;
- (iv) full details in respect of the Medical Device supplied to that Te Whatu Ora Hospital in accordance with this Agreement, including the:
 - (A) quantity of the Medical Device supplied;
 - (B) price of the Medical Device;
 - (C) total cost for the total amount of the Medical Device supplied; and
 - (D) any other information that a Te Whatu Ora Hospital requires you to supply.
- (b) Paragraph (a) does not apply to the extent that both parties have agreed to alternative or varied invoicing arrangements in respect of a particular Medical Device or Medical Devices and this is expressly set out in Part 8 and/or Part 9.

22.2 Logistics Provider placing the Purchase Order

- (a) Where a Purchase Order has been received from a Logistics Provider (regardless of where the Medical Device is to be delivered) you are to invoice the particular Logistics Provider at the end of each month, but no later than the second business day following the month to which the invoice in respect of the Medical Device relates, specifying for the Medical Device supplied during that month:
 - (i) your delivery note reference number;
 - (ii) the particular Logistics Provider's Purchase Order reference number;
 - (iii) the net amount payable in respect of the Medical Device supplied pursuant to a Purchase Order placed by a Logistics Provider in accordance with this Agreement;
 - (iv) full details in respect of the Medical Device supplied pursuant to a Purchase Order placed by a Logistics Provider in accordance with this Agreement, including the:
 - (A) quantity of the Medical Device supplied;
 - (B) price of the Medical Device;
 - (C) total cost for the total amount of the Medical Device supplied; and
 - (D) any other information that Logistics Provider requires you to supply.
- (b) Paragraph (a) does not apply to the extent that both parties have agreed to alternative or varied invoicing arrangements in respect of a particular Medical Device or Medical Devices and this is expressly set out in Part 8 and/or Part 9.

23. Payment

- (a) Provided that the Medical Device has been supplied in accordance with this Agreement, and the particular Te Whatu Ora Hospital or Logistics Provider (as applicable) receives an invoice in accordance with clause 22 above or any special

invoicing arrangements in Part 8 and/or Part 9, payment by the Te Whatu Ora Hospital or Logistics Provider (as applicable) to you of the amount required to be paid by it is expected to occur:

- (i) by electronic funds transfer or such other method of payment as is designated by that Te Whatu Ora Hospital or Logistics Provider (as applicable); and
 - (ii) on the 20th day of the month following the month to which the invoice for the Medical Device relates, or, if the 20th day of the month is not a business day, then on the next business day following the 20th day of the month.
- (b) The particular Te Whatu Ora Hospital's or Logistics Provider's failure to dispute any invoice prior to payment does not prejudice that Te Whatu Ora Hospital's or Logistics Provider's right subsequently to dispute the correctness of such an invoice, nor its ability to recover any amount of overpayment from you.
 - (c) The Te Whatu Ora Hospital or Logistics Provider (as applicable) may withhold, deduct or set off the amount of any overpayment or any amount recoverable by that Te Whatu Ora Hospital or Logistics Provider (as applicable) from you under this Agreement from any future amount owing to you.
 - (d) You must not withhold delivery of Medical Devices under this Agreement to any Te Whatu Ora Hospital or Logistics Provider on account of another Te Whatu Ora Hospital or Logistics Provider not having paid an invoice as required under this Agreement.
 - (e) For the avoidance of doubt, Pharmac does not guarantee the payment of any invoice under this Agreement.
 - (f) This clause 23 confers a benefit on (and is enforceable by) Te Whatu Ora Hospitals and Logistics Providers (as applicable) in accordance with the Contract and Commercial Law Act 2017, Part 2, Subpart 1.

PART 5: Reporting and audit

24. Reporting

24.1 Performance reporting

- (a) You will report to Pharmac, in writing and otherwise in a form to be prescribed by Pharmac, on a quarterly basis on the last business day of January, April, July and October in each year in respect of the previous three calendar months (or such shorter period in respect of the first quarterly report), in relation of the matters specified in paragraph 1 of Schedule 3 (each report a **KPI Report**).
- (b) You agree to provide such further reports and/or information regarding this Agreement as is reasonably required by Pharmac for Pharmac's contract monitoring, data analysis, reporting, and related purposes including but not limited to reporting on the Purchase Orders received from a Te Whatu Ora Hospital or Logistics Provider.

24.2 Price and volume data

- (a) You agree to provide to Pharmac, on a quarterly basis on the last business day of January, April, July and October in each year in respect of the previous three calendar months (or such shorter period in respect of the first quarterly report), sales data (including a complete list of purchases by each Te Whatu Ora Hospital or Logistics Provider (if applicable)) for each Medical Device (each report a **Sales Report**). Each Sales Report must include the details as set out in paragraph 3(a) of Schedule 3.
- (b) You acknowledge that Pharmac may invoke its rights under clause 25 to audit any Sales Report provided by you under this clause 24.2.
- (c) Notwithstanding any other provisions in this Agreement, including clause 37 regarding confidential information, you agree that a Te Whatu Ora Hospital or Logistics Provider may provide Pharmac and its agents with any price and volume data held by that Te Whatu Ora Hospital or Logistics Provider in respect of a Medical Device covered by this Agreement and Pharmac and its agents may provide any such data supplied by way of a Sales Report to Te Whatu Ora Hospitals or Logistics Providers.
- (d) You agree that Pharmac will retain any data received by way of a Sales Report for at least seven (7) years from the date of receipt of the information. Such data retained will be used by Pharmac for the purposes of fulfilling its statutory function, including in the course of conducting future procurement activities in respect of medical devices of the product type and kind covered by this Agreement.

24.3 Supply issues reporting

- (a) You will provide Pharmac with regular reports, at a frequency notified by Pharmac to you from time to time, on any potential Failure to Supply a Medical Device, including all details as required by paragraph 4 of Schedule 3 (each report a **Supply Issues Report**).

25. Audit

- (a) Pharmac may, from time to time, review your records that you hold that relate to this Agreement with regard to stock levels, registration information and supply issues, for the purposes of auditing your compliance with this Agreement. In these circumstances, Pharmac, in consultation with you, will determine the terms and manner of any such audit, which as a minimum, must include the following:
 - (i) the audit will be conducted by an auditor authorised by Pharmac;
 - (ii) you agree to co-operate fully with Pharmac and provide Pharmac and the auditor with all reasonable assistance to ensure that any audit conducted under this clause is fully and properly completed to Pharmac's satisfaction, including:
 - (A) allowing the auditor access to your premises, records and other information you hold that relates to this Agreement with regard to stock levels, registration information and supply issues for the purposes of, and during the course of, conducting the audit; and
 - (B) answering promptly any questions from Pharmac or the auditor concerning any aspect of your compliance with this Agreement; and
 - (iii) Pharmac will give you ten (10) business days' notice of its intention to conduct an audit under this clause and will ensure that the conduct of any such audit, and access in terms of (A) above, does not unreasonably disrupt your business operations.
- (b) Pharmac will notify you in writing if an audit under this clause reveals any non-compliance with this Agreement. You and Pharmac, acting reasonably, shall endeavour to agree the actions that you will take to remedy the non-compliance within ten (10) business days of receipt of this notification from Pharmac. Regardless of whether an agreement is reached or not, you will act promptly to remedy the non-compliance and will report to Pharmac on the actions you have taken within thirty (30) business days of receipt of this notification from Pharmac.
- (c) Pharmac may terminate the Agreement if you fail to remedy any area of non-compliance in accordance with (b).

PART 6: Supply obligations and Failure to Supply

26. Supply obligations

26.1 Stock holdings

The minimum requirement for the amount of stock of a Medical Device that must be held by you in New Zealand and available for supply to Te Whatu Ora Hospitals at any given time is the greater of:

- (a) three-quarters of your most recent four months' total sales of that Medical Device;
- (b) your forecast sales demand of that Medical Device for the next three-month period;
- (c) the volume of stock of that Medical Device that was required to supply the orders for the three-month period with the highest sales in the previous 12 month period; or
- (d) one-quarter of the normal number of units of that Medical Device ordered by Te Whatu Ora Hospitals or Logistics Providers (as applicable) per year,

unless otherwise specified in Part 8 and/or Part 9 of this Agreement.

26.2 Continuity of supply

- (a) You must supply, and continue to supply, the Medical Device(s) on the terms set out in, and in accordance with, this Agreement including holding sufficient stock to enable you to fully fill all orders as they are received in accordance with clause 26.1 and the requirements relating to delivery and delivery timeframes set out in clause 16.
- (b) You warrant that you have entered into contractual and other arrangements to the extent necessary to ensure that you meet your obligations under (a) above. You therefore acknowledge that any failure to meet these obligations that is attributable (without limitation) to:

- (i) any failure on the part of a person in the relevant Medical Device supply chain;
or
- (ii) any act or omission by a related entity or sub-contractor of yours,

is not considered by Pharmac to be a Force Majeure Event for the purposes of clauses 27.2, 28.2, and 28.3 below.

- (c) On request of a Te Whatu Ora Hospital or Pharmac, you must provide the requesting Te Whatu Ora Hospital or Pharmac with either:
 - (i) a copy of your current Business Continuity Plan; or
 - (ii) provide written assurances to Pharmac's or the Te Whatu Ora Hospital's satisfaction,

which demonstrate the continuity of supply arrangements you have in place with respect to all of the Medical Devices.

- (d) In the event Pharmac learns of your potential Failure to Supply a Medical Device in accordance with this Agreement (whether you notify Pharmac under this Agreement or otherwise), you agree that Pharmac may inform other suppliers of your potential Failure to Supply, including providing such other suppliers with sufficient information to allow those suppliers to adequately prepare for a potential increase in demand.

27. Managing potential Failure to Supply

27.1 Notification and consultation

- (a) In addition to your reporting obligations in clause 24 but subject to (b) below, you must notify Pharmac and the relevant Te Whatu Ora Hospital(s) (or Logistics Provider(s), if applicable) in writing as soon as you have reason to believe you may fail to supply a Medical Device in accordance with this Agreement for any reason, including where:
 - (i) your stock holdings fall below the minimum requirement set out in clause 26.1;
 - (ii) you become aware of a defect, or possible defect, associated with a Medical Device;
 - (iii) you recall (or suspect you may recall), or are (or suspect you may be) required by governmental or any other authorities to recall or modify, any or all of the Medical Devices;
 - (iv) you become aware of any manufacturer supplied or independently sourced reputable reports of non-compliance that genuinely affects or has the potential to affect the safety of the Medical Devices;
 - (v) you become aware of any issue that may impact on your ability to fulfil a Purchase Order in full and on time (in accordance with the requirements for delivery and delivery timeframes in clause 16); or
 - (vi) you plan any changes to your ordering or delivery systems that may affect a Te Whatu Ora Hospital or Logistics Provider.
- (b) In the event of your Failure to Supply or potential Failure to Supply as described in (a)(i) to (a)(vi) that is Low Risk (as defined in paragraph 4(c) of Schedule 3), you need not notify Pharmac and may instead resolve the issue with the relevant Te Whatu Ora Hospitals and Logistics Providers (as applicable).
- (c) In the event you submit a Supply Issues Report to Pharmac in accordance with paragraph 4 of Schedule 3, or you notify Pharmac and a Te Whatu Ora Hospital or Logistics Provider (as applicable) of a potential Failure to Supply under (a) above, you must also identify and explain any steps that you have taken or will take to remedy the risk of the potential Failure to Supply, including the steps you have taken to procure an Alternative Medical Device as required by clause 27.2(a)(i).
- (d) You acknowledge that Pharmac and/or the Te Whatu Ora Hospital(s) or Logistics Provider(s) (as applicable) may wish to consult with you in respect of any steps that you advise them of under (c) above or any other steps that may be required to remedy the potential Failure to Supply, and you agree that you will engage and cooperate with Pharmac and/or the Te Whatu Ora Hospital(s) or Logistics Provider(s) (as applicable), as required.
- (e) Where you comply with the notification and consultation obligations in this clause 27.1, no liquidated damages in respect of any Failure to Supply will be payable.

27.2 Supply of Alternative Medical Device

- (a) Subject to (d) below, if you fail to supply a Medical Device in accordance with this Agreement, whether as a result of your inability to meet demand for supply, your inability to deliver, the Medical Device being recalled, the Medical Device being defective or for any other reason, for more than 1 business day to any Te Whatu Ora Hospital (or a Logistics Provider, if applicable), then:
- (i) you must use your best endeavours to source, within what the relevant Te Whatu Ora Hospital (or Logistics Provider, if applicable) considers to be a reasonable period of time, an Alternative Medical Device for supply to any Te Whatu Ora Hospital or Logistics Provider site as noted on the original Purchase Order at the Price; and
 - (ii) if you fail to source an Alternative Medical Device at the Price in accordance with (i) above (other than for reasons that Pharmac considers to be a Force Majeure Event) then, at Pharmac's option:
 - (A) you must pay to all relevant Te Whatu Ora Hospitals (and/or Logistics Provider(s), if applicable) any additional costs incurred by such Te Whatu Ora Hospitals (and/or Logistics Provider(s), if applicable) as a result of the procurement of the Alternative Medical Device; or
 - (B) Pharmac may implement an arrangement with another supplier to supply an Alternative Medical Device (including an arrangement for back-up supply), and you must pay to all relevant Te Whatu Ora Hospitals (and/or Logistics Provider(s), if applicable) any additional costs incurred by such Te Whatu Ora Hospitals (and/or Logistics Provider(s), if applicable) as a result of the procurement of the Alternative Medical Device.
- (b) For the purpose of providing an Alternative Medical Device as contemplated under (a)(i), you agree to work closely with Pharmac in order to agree on, source and provide an Alternative Medical Device. This will include obtaining Pharmac's consent to the supply of the Alternative Medical Device as a substitute for the Medical Device, unless the relevant situation is Low Risk (as defined in paragraph 4(c) of Schedule 3) or supply is Genuinely Urgent.
- (c) For the purposes of (b) above, "**Genuinely Urgent**" means a situation where Pharmac is not available to provide consent in respect of the Alternative Medical Device (for example where the situation occurs outside of Pharmac's normal operating hours), a Te Whatu Ora Hospital (and/or Logistics Provider) identifies an urgent need for an Alternative Medical Device and the delay in obtaining Pharmac's consent for the Alternative Medical Device is likely to increase the risk to patients or negatively impact Te Whatu Ora's ability to deliver services. All Genuinely Urgent situations must be notified to Pharmac immediately for Pharmac's review.
- (d) Nothing in (a) above that confers an obligation on you will apply where your Failure to Supply a Medical Device occurs solely as a result of a competing supplier's failure to supply, and:
- (i) Pharmac did not notify you of that supplier's supply failure or of the potential for that supplier to suffer a supply failure; or
 - (ii) Pharmac did notify you of that supplier's supply failure or of the potential for that supplier to suffer a supply failure, and you used your best endeavours to make provision for an increase in demand,

provided that in each case you show evidence to support your position (where Pharmac requests such evidence). Pharmac will act reasonably in requesting and

relying on such evidence. For the avoidance of doubt, this clause 27.2(d) does not affect any other clause under this Part 6, and in particular does not relieve you of your obligations set out in clauses 26.2 and 27.1.

This clause 27.2 applies in respect of each Category of Medical Device.

27.3 Defective Medical Devices

- (a) Without limiting any other remedies available to Pharmac or any Te Whatu Ora Hospital, you will rectify any defects associated with the Medical Devices at no extra cost to Pharmac or the Te Whatu Ora Hospital.
- (b) If any Medical Device fails to comply with the requirements of this Agreement or the Contract and Commercial Law Act 2017, Part 3, Subparts 1-6, such Medical Device may be rejected and not paid for by the Te Whatu Ora Hospital or Logistics Provider (as applicable). Any Medical Device rejected by the Te Whatu Ora Hospital or Logistics Provider (as applicable) will, upon demand, be returned to you at your risk and expense. You are required to pay the Te Whatu Ora Hospital's or Logistics Provider's reasonable costs of returning the Medical Devices to you (along with any costs that the Te Whatu Ora Hospital or Logistics Provider incurs in respect of collecting the Medical Devices to return to you, if applicable) upon receiving written notice from the Te Whatu Ora Hospital or the Logistics Provider of the costs incurred.

27.4 Recalls and safety concerns

- (a) In the event of a recall or safety concern in respect of a Medical Device, in addition to your notification obligations under clause 27.1(a), you must also notify Medsafe (in the case of a recall, where the Ministry of Health has not required the recall itself).
- (b) You must comply with any recall requirements specified by the Ministry of Health (in its own right or through Medsafe), including the requirement to have a recall procedure in place that complies with the Ministry of Health's publication on this topic.
- (c) Notwithstanding your obligation under clause 27.2 in respect of supplying an Alternative Medical Device, the Te Whatu Ora Hospital or Logistics Provider (as applicable) reserves its right to procure alternative products elsewhere if the Te Whatu Ora Hospital or Logistics Provider has concerns about the safety of the Medical Device or does not wish to use the Alternative Medical Device.

28. Consequences of Failure to Supply

28.1 Consequences of defective/undelivered/recalls and safety concerns in respect of Medical Devices

In the event that any Medical Device is rejected under clause 27.3(b), is undelivered, or is recalled:

- (a) you shall immediately refund to the Te Whatu Ora Hospital or Logistics Provider (as applicable) all money paid by the Te Whatu Ora Hospital or Logistics Provider (as applicable) for or on account of such Medical Device (including any Medical Device already used in respect of a patient that cannot practically be returned in whole by the Te Whatu Ora Hospital or Logistics Provider), unless you have provided an Alternative Medical Device to the satisfaction of the Te Whatu Ora Hospital or Logistics Provider (as applicable). That refund will be recoverable from you as a debt due to the Te Whatu Ora Hospital or Logistics Provider (as applicable); and

- (b) without prejudice to any other remedies which it may have, the Te Whatu Ora Hospital or Logistics Provider may immediately cancel all or part of its order for the Medical Device on giving notice to you and may procure alternative product elsewhere. Any additional costs incurred by Pharmac or the Te Whatu Ora Hospital or Logistics Provider (as applicable) in procuring such alternative product, including any difference between the contract price and the actual cost of procuring the alternative products (if it is higher) will be paid to Pharmac, the Te Whatu Ora Hospital or Logistics Provider (as applicable) by you on demand and will be recoverable from you as a debt due to the Te Whatu Ora Hospital or Logistics Provider (as applicable).

28.2 Indemnity for Failure to Supply

- (a) Subject to (b) below, you agree to indemnify the Te Whatu Ora Hospital and, if applicable, the Logistics Provider, if for any reason you fail to supply a Medical Device on the terms set out in, and in accordance with, this Agreement (other than for reasons Pharmac considers to be a Force Majeure Event). This indemnity covers all additional costs incurred by the Te Whatu Ora Hospital and, if applicable, the Logistics Provider (or by Pharmac on their behalf) as a result of your Failure to Supply the Medical Device in accordance with this Agreement, including any additional costs:
 - (i) relating to procuring or funding any Alternative Medical Device(s);
 - (ii) any additional administration, surgery, patient appointment, patient care costs;
 - (iii) other similar costs in relation to rectifying a recall situation; and
 - (iv) all actual legal expenses.
- (b) The obligation to indemnify the Te Whatu Ora Hospital and, if applicable, the Logistics Provider under this clause 28.2 will not apply where your Failure to Supply a Medical Device occurs solely as a result of a competing supplier's failure to supply, and:
 - (i) Pharmac did not notify you of that supplier's supply failure or of the potential for that supplier to suffer a supply failure; or
 - (ii) Pharmac did notify you of that supplier's supply failure or of the potential for that supplier to suffer a supply failure, and you used your best endeavours to make provision for an increase in demand,

provided that in each case you show evidence to support your position (where Pharmac requests such evidence). Pharmac will act reasonably in requesting and relying on such evidence. For the avoidance of doubt, this clause 28.2(b) does not affect any other clause under this Part 6, and in particular does not relieve you of your obligations set out in clauses 26.2 and 27.1.

28.3 Liquidated damages

- (a) Subject to clause 27.1(e) above (which provides that where you comply with the notification and consultation obligations in clause 27.1, no liquidated damages in respect of any Failure to Supply will be payable), if you fail to supply a Medical Device in accordance with this Agreement for any reason (other than for reasons that Pharmac considers to be a Force Majeure Event), then in addition to your obligations under clause 27.2, you must pay to Pharmac (for the benefit of Pharmac and Te Whatu Ora Hospitals) liquidated damages for the administrative and/or operational costs incurred by Pharmac and Te Whatu Ora Hospitals as a result of your Failure to Supply in the amount of \$25,000 per Medical Device.
- (b) You acknowledge and agree that:

- (i) the amount of liquidated damages in this clause represents a reasonable estimate of the administrative and operational costs incurred by Pharmac and Te Whatu Ora Hospitals (including the use of staff and loss of opportunity as a result of use of staff time, and communication costs), the estimate being based on Pharmac's and Te Whatu Ora Hospitals' previous experience; and
- (ii) the amount referred to as liquidated damages is not intended to include any penalty element nor any amount for costs relating to the securing of an Alternative Medical Device, or the procurement of an Alternative Medical Device,

provided that Pharmac may, in its sole discretion, require you to pay less than the amount specified as liquidated damages if it is satisfied that the actual costs in the particular circumstances are less than the amount so specified.

- (c) The amount referred to in this clause is plus GST (if any).

28.4 Default interest and recovery costs

If payment of any amount required to be paid by you under this clause 28 is not made by you, in full, by the due date for payment of that amount as notified to you in writing by Pharmac, then:

- (a) interest will accrue on such sum as remains unpaid as a rate per annum, equal to the business base rate of the ASB Bank Limited plus five percentage points, calculated and compounded on a daily basis, from the due date until such time as the sum due (including interest) is paid in full. This obligation to pay default interest is to arise without the need for a notice or demand from Pharmac for such default interest; and
- (b) Pharmac may take any action, including legal action, without first needing to implement the dispute resolution contained in clause 31 below, to recover that amount and you agree to pay Pharmac actual enforcement costs incurred in relation to that action.

29. Privity of contract

This Part 6 confers a benefit on (and is enforceable by) Te Whatu Ora Hospitals and Logistics Providers in accordance with the Contract and Commercial Law Act 2017, Part 2, Subpart 1.

PART 7: General terms

30. Termination

30.1 Termination

- (a) Without in any way limiting Pharmac's other rights under this Agreement or the OPPs, Pharmac may terminate this Agreement for any reason and without cause upon giving three (3) months' notice in writing to you.
- (b) You may terminate this Agreement for any reason and without cause upon giving six (6) months' notice in writing to Pharmac.
- (c) Pharmac may terminate this Agreement immediately in writing if:
 - (i) you are insolvent or unable to pay your debts as they fall due, enter into any compromise or arrangement with your creditors, are wound up, or have a liquidator, provisional liquidator, receiver or official manager appointed over all or any of your property;
 - (ii) you breach this Agreement and you fail to remedy the breach within ten (10) business days of Pharmac having given notice to you of such breach;
 - (iii) you indicate by words or conduct that you do not intend to perform some, all, or any of your future obligations under this Agreement; or
 - (iv) termination is required by a decision of a regulatory authority which is binding on Te Whatu Ora Hospitals.

30.2 Supply upon termination

Notwithstanding the termination of this Agreement, you will fulfil Purchase Orders issued up to and including the date on which termination becomes effective.

31. Dispute resolution

- (a) If there is a dispute between us arising out of, or in connection with, this Agreement, neither of us is to commence any proceedings relating to that dispute until the following procedure has been complied with:
 - (i) the party claiming a dispute has arisen must give written notice to the other party specifying the nature of the dispute;
 - (ii) we will endeavour, in good faith, to resolve the dispute referred to in the notice by using informal dispute resolution techniques;
 - (iii) if we have not resolved the dispute within fourteen (14) days after the date notice of a dispute was given, we may agree that the dispute is to be:
 - (A) mediated according to the standard mediation agreement of the Resolution Institute (a body corporate incorporated in Australia and registered as an overseas company in New Zealand), and the Chair of

the Resolution Institute (or the Chair's nominee) will select the mediator and determine the mediator's remuneration, we are unable to agree on such matters; or

- (B) submitted to arbitration in accordance with the Arbitration Act 1996, with such arbitration being conducted by a single arbitrator to be agreed on by the parties or, failing agreement, the Chair of the Resolution Institute (or the Chair's nominee) will select the arbitrator.
 - (iv) a party seeking urgent interlocutory relief may, by notice to the other party, elect not to comply with the provisions of this clause, but only to the extent of the relief sought, and only for the period required to dispose of the application for interlocutory relief; and
 - (v) pending resolution of the dispute, this Agreement will remain in full effect without prejudicing our respective rights and remedies (including Pharmac's rights under its OPPs).
- (b) For the avoidance of doubt you acknowledge and agree that Pharmac may elect to involve Te Whatu Ora , in any part, or all, of the above procedure.

32. Litigation support

If this Agreement or its terms (including the basis on which a Medical Device is listed):

- (a) give rise to proceedings being issued against Pharmac; or
- (b) result in Pharmac being made a party to any proceedings issued by a third party,

you will give Pharmac all assistance it reasonably requires to gather evidence (including expert medical and clinical evidence) for the purpose of those proceedings.

33. Intellectual property

You agree not to use intellectual property claims to impede any Te Whatu Ora Hospital's freedom to utilise the Medical Devices or to impede Pharmac from using any information provided to it by you in accordance with this Agreement.

34. Liability

You acknowledge and agree that liability for paying any invoice under this Agreement lies with the relevant Te Whatu Ora Hospital or Logistics Provider that placed the Purchase Order, or, in respect of Consignment Medical Devices, used the Medical Device and is not joint and several with that of any other Te Whatu Ora Hospital, Logistics Provider or Pharmac and that the relevant Te Whatu Ora Hospital or Logistics Provider is solely responsible for its obligations in respect of the Medical Devices and any associated services supplied to that Te Whatu Ora Hospital or Logistics Provider under this Agreement. No Te Whatu Ora Hospital or Logistics Provider will be liable in any way whatsoever (including without limitation in respect of any liability for monies owed to you) in respect of any act, error or omission of any other Te Whatu Ora Hospital or Logistics Provider in connection with this Agreement.

35. Indemnity for negligent provision or breach of intellectual property rights

- (a) You indemnify each Te Whatu Ora Hospital and, if applicable, each Logistics Provider, and Pharmac from and against any claims, proceedings, damages, losses, liability costs and expenses (including legal and expert costs and expenses incurred on a solicitor/client basis) suffered or incurred by the Te Whatu Ora Hospital, Logistics Provider or Pharmac which arise as a result of the negligent provision of the Medical Devices by you.
- (b) You indemnify and will keep indemnified each Te Whatu Ora Hospital, Logistics Provider and Pharmac from and against all damages, losses, liability, costs and expenses, including legal fees, incurred by the Te Whatu Ora Hospital, Logistics Provider and/or Pharmac (as applicable) arising out of, or in connection with, any claim or threatened claim alleging that any of the Medical Devices or any services, information or materials supplied by you under this Agreement, or a Te Whatu Ora Hospital's use or possession of any of them, infringes the Intellectual Property Rights of any person.

36. Insurance

- (a) You shall ensure your risks are covered under this Agreement, whether by insurance or otherwise. If requested you will send a copy of any relevant insurance policies to Pharmac and each Te Whatu Ora Hospital. Whether or not insurance policies exist shall not derogate from your potential liability under this Agreement.
- (b) If applicable Part 8 and/or Part 9 shall include any specific insurance requirements, which are required for any Medical Device.

37. Confidentiality

- (a) Information relating to the terms of this Agreement, or any other information exchanged during negotiation of this Agreement or otherwise, that is agreed in writing by both of us as being confidential ("**Confidential Information**") is confidential to us and our employees, legal advisers and other consultants (including PTAC and its sub-committees and any medical device advisory committee that may be established by Pharmac), the Ministry of Health, Te Whatu Ora and Te Whatu Ora Hospitals (if applicable). You acknowledge that it may be necessary or appropriate for Pharmac to disclose Confidential Information:
 - (i) pursuant to the Official Information Act 1982; or
 - (ii) in the course of consultation on this Agreement; or
 - (iii) in publicly notifying any approval of this Agreement by the Pharmac Board or by Pharmac personnel under delegated authority; or
 - (iv) otherwise pursuant to Pharmac public law or any other legal obligations.
- (b) Pharmac may consult with you before deciding whether to disclose Confidential Information for the purposes described in (a)(i) to (iv) above, in order to ascertain any objections you may have to the disclosure of any Confidential Information. You acknowledge, 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. Outside the circumstances described in (a)(i) to (iv) above, Confidential

Information must not be disclosed by either of us (or by our employees, legal advisers and other consultants) unless:

- (i) the information is publicly available without any cause attributable to the disclosing party; or
- (ii) the other party has been reasonably informed prior to disclosure, and the disclosure is:
 - (A) for the purposes of this Agreement; or
 - (B) required by law; or
 - (C) in a form, and of content, agreed to by us.
- (c) For the avoidance of doubt:
 - (i) generalised aggregated information regarding the Medical Devices that does not identify you, or that cannot reasonably be expected to identify you, is not Confidential Information and Pharmac may use and publish such information as it sees fit;
 - (ii) information released by Pharmac in accordance with (a)(i) to (iv) above ceases to be Confidential Information and you agree that Pharmac may release that information again at any time in the future without consulting with you or obtaining your prior agreement.

38. Relationship between the parties

Nothing in this Agreement constitutes a legal relationship between the parties in the nature of a partnership, joint venture, agency or employment. You are responsible for the liability of your own, and your Personnel's, salary, wages, holiday or redundancy payments and any GST, corporate, personal and withholding taxes, ACC premiums or other levies attributable to your business or the engagement of your Personnel.

39. Notices

Any notice under this Agreement may be made by email, letter or facsimile to the addresses advised by one Party to the other.

40. Probity

- (a) You acknowledge that Te Whatu Ora is a Crown entity under the Crown Entities Act 2004. It is therefore essential that you always act in your dealings with the Te Whatu Ora Hospital, its advisors, employees, agents, and any Logistics Providers acting on its behalf in a manner consistent with the highest standards of probity and you must conform to any probity guidelines and principles advised by Pharmac from time to time.
- (b) You will:
 - (i) adhere to all requirements of the Te Whatu Ora Hospitals' probity and any other policy documents relating to sponsorship, gifts, hospitality, inducements or similar, such as declaration, authorisation and probity register requirements.

The Te Whatu Ora Hospital will provide you with a copy of its relevant policy documents on request; and

- (ii) provide Te Whatu Ora Hospitals with any evidence they may request to satisfy them that the above policy requirements have been complied with.

41. Time of the essence

Time is of the essence in relation to performance of your obligations under this Agreement.

42. No derogation

For the avoidance of doubt, the express provision of a remedy for, or consequence of, breach of any term of this Agreement does not derogate from any other legal right or remedy available to Pharmac under this Agreement or otherwise in respect of such breach.

43. No waiver

A failure or delay by either of us to exercise any right arising under this Agreement is not a waiver of that right, and a waiver of a breach of this Agreement is not a waiver of any other breach.

44. Invalidity

If any part of this Agreement is held to be invalid, unenforceable or illegal for any reason, this Agreement will be deemed to be amended by the addition or deletion of wording necessary to remove the invalid, unenforceable or illegal part, but otherwise to retain the provisions of this Agreement to the maximum extent permissible under New Zealand law.

45. Agreement prevails

Where any of your terms of supply, whether recorded on your invoices or in credit arrangements entered into or elsewhere, conflict with or detract from any of the terms of this Agreement, the terms of this Agreement will prevail and will apply to the exclusion of any of your terms or documentation.

46. Entire agreement

This Agreement:

- (a) is the entire agreement between us regarding the terms on which each Medical Device is listed in Section H, Part III of the Pharmaceutical Schedule and procured by Te Whatu Ora Hospitals; and
- (b) supersedes and extinguishes all prior agreements and understandings between us, and between you and Te Whatu Ora, and any prior agreements and understandings originally entered into between you and district health boards (as applicable) regarding supply of each Medical Device.

47. Advertising

You must not procure, or in any way participate or assist in, the publishing of any Advertisement that:

- (a) is aimed at patients in respect of whom medical devices are used; and
- (b) which breaches any applicable:
 - (i) statute or regulation, including the Fair Trading Act 1986, Medicines Act 1981 and Medicines Regulations 1984, Medicines (Database of Medical Devices) Regulations 2003; or
 - (ii) industry standard, including the Advertising Standards Authority Codes of Practice, the Medicines New Zealand Code of Practice or the Medical Technology Association of New Zealand Code of Practice.

For the purposes of this clause:

- (c) **“Advertisement”** means any words, whether written, printed or spoken, any pictorial representation or design, any sounds or visual images, or combination of sounds and visual images, or any other form of communication used or appearing to be used to promote:
 - (i) the sale of a Medical Device; or
 - (ii) the use of a method of treatment involving a Medical Device; and
- (d) references to a statute, regulation or industry standard include that statute, regulation or industry standard as amended or replaced from time to time.

48. Contracts privity

- (a) For the purposes of the Contract and Commercial Law Act 2017, Part 2, Subpart 1, we both acknowledge that your obligations in this Agreement constitute promises which confer or are intended to confer a benefit on Te Whatu Ora and related persons (including, where relevant, a Logistics Provider), and are enforceable at the suit of Te Whatu Ora or any such persons (including, where relevant, a Logistics Provider).
- (b) Except as expressly provided in (a) above, the parties do not intend to create rights in, or grant remedies to, any third party as a beneficiary of this Agreement, and all the provisions of this Agreement shall be for the sole and exclusive benefit of the parties.

49. No reliance

You acknowledge that you have entered into this Agreement in reliance on your own knowledge, skill and independent advice, and not in reliance on any representations made, or any information made available to you, by Pharmac.

50. Amendments

Amendments to this Agreement are only effective where the parties:

- (a) have agreed to adjust the Price of each Medical Device listed or referenced in Schedule 1 in accordance with clause 21.1(h) or clause 21.2(d)(i);
- (b) have agreed in writing between authorised representatives any other amendment to this Agreement.

51. Assignment and sub-contracting

You will not permit any part of this Agreement to be transferred, assigned or sub-contracted (either directly or due to a change of ownership or control) without Pharmac's prior written consent (such consent not to be unreasonably withheld). You will provide Pharmac with a minimum of six weeks prior written notice of the proposed effective date of the transfer, assignment, sub-contracting (including the date of the change of ownership or control (where applicable)). Any such consent may be given subject to such reasonable conditions as Pharmac sees fit, but no such consent will relieve you from any liability or obligation under the terms of this Agreement, and you will continue to be responsible for the acts, defaults and neglects of your transferee, assignee or sub-contractor.

52. Further Assurances

We both agree to execute any further documents and do any further acts within our power as may be reasonably necessary from time to time to give effect to the terms and intentions of this Agreement.

53. Survival

Should this Agreement end, your rights and the rights of Pharmac, each Te Whatu Ora Hospital and each Logistics Provider (if applicable) do not end, in that rights which have accrued or arose from a breach prior to the end of this Agreement will continue, together with obligations of confidentiality.

54. Governing law and jurisdiction

This Agreement is governed by, and is to be construed in accordance with, the laws of New Zealand. Each party irrevocably submits to the jurisdiction of the New Zealand courts for the purpose of hearing and determining all disputes under or in connection with this Agreement.

55. Definitions

In this Agreement:

"Agreement" means this agreement including all Schedules and Annexures;

"Alternative Medical Device" means an alternative medical device, having an equivalent therapeutic use as the relevant Medical Device, that Pharmac or the Te Whatu Ora Hospital considers is an acceptable substitute for a Medical Device;

“Business Continuity Plan” means a plan setting out how you will ensure that you are able to continue to supply each Medical Device in the event of a disruption to any stage of your ordinary business operations;

“Category of Medical Device” means a specific range of Medical Device as set out in Part 8 and/or Part 9 of this Agreement;

“Consignment Medical Devices” means a Medical Device to be placed on consignment in a Te Whatu Ora Hospital’s premises in accordance with clause 15;

“Crown Direction” means any Ministerial direction given to Pharmac under section 103 of the Crown Entities Act 2004;

“Failure to Supply” means your failure to supply a Medical Device in accordance with the terms of this Agreement, for whatever reason;

“Force Majeure Event” means any cause preventing the affected party from performing any or all of its obligations under this Agreement which arises from or is attributable to acts, events, omissions or accidents beyond the reasonable control of the affected party, which:

- (a) was not reasonably foreseeable;
- (b) could not have been avoided or mitigated through the exercise of good industry practice and due care, skill and diligence; and
- (c) was not caused by the affected party, its affiliates, officers, Personnel or suppliers,

but does not include any lack of finance or financial means or any changes in market conditions;

“Intellectual Property Rights” means copyright and all intellectual property rights and interests conferred under statute, common law or equity in relation to trademarks, designs, inventions (including patents), confidential information, know-how, and all other proprietary rights, whether registered or unregistered, and all equivalent rights and forms of protection anywhere in the world;

“KPI Report” means a key performance indicator report provided to Pharmac under clause 24.1;

“Loan” means the supply of Medical Devices by you to a Te Whatu Ora Hospital for use for a specified period or event and may include long term lease, daily rent or rent to buy as listed or referenced in Schedule 1 and “loaned” is to be interpreted accordingly;

“Loan Medical Devices” means those Medical Devices that are supplied on a Loan basis;

“Logistics Provider” means an entity contracted by a Te Whatu Ora Hospital to arrange the procurement of and/or take delivery of a Medical Device required by the Te Whatu Ora Hospital;

“Medical Device” means any medical device listed or referenced in Schedule 1;

“Medicines Act” means the Medicines Act 1981 (as amended from time to time);

“Medsafe” means the business unit by that name within the Ministry of Health that has responsibilities in relation to the safety of medicines and medical devices used and supplied in New Zealand (including regulatory and oversight responsibilities) or any alternative agency that takes over regulatory responsibility or responsibility for the safety of medical devices supplied in New Zealand;

“Performance Standards” means the performance standards listed in Schedule 3;

“Permits” includes any statutory licences, permits, quotas, consents, planning permissions and other authorisations under or pursuant to any statute or regulation;

“Personnel” means all individuals engaged by the relevant party in relation to this Agreement. Examples include the owner of the business, its directors, employees, subcontractors, agents, external consultants, specialists, technical support and co-opted or seconded staff;

“Pharmac” means the Pharmaceutical Management Agency continued under the Pae Ora (Healthy Futures) Act 2022;

“Pharmaceutical Schedule” means the pharmaceutical schedule produced by Pharmac pursuant to section 69(1)(a) of the Pae Ora (Healthy Futures) Act 2022;

“Price” means the price (exclusive of GST) at which a Medical Device is to be supplied or sold, or made available for supply or sale, by you to, at a Te Whatu Ora Hospital’s discretion, the Te Whatu Ora Hospital or Logistics Provider (as applicable);

“Product Specification” means a product specification for a Medical Device set out in Schedule 2;

“Purchase Order” means an order for the purchase of Medical Device(s) as described in clause 14 or, in the case of Loan Medical Devices, an order for the supply of Medical Device(s) on a Loan basis (unless otherwise specified in Part 8 and/or Part 9);

“PTAC” means the Pharmacology and Therapeutics Advisory Committee;

“Safety Data Sheet” means a standard document provided by the manufacturer of a hazardous substance. The document describes the potential hazards, physical properties, and procedures for safe use of the substance;

“Sales Report” means a report provided to Pharmac under clause 24.2;

“Supply Issues Report” means a report submitted to Pharmac in accordance with paragraph 4 of Schedule 3;

“Te Whatu Ora” means Health New Zealand, a Crown agent established under section 11 of the Pae Ora (Healthy Futures) Act 2022;

“Te Whatu Ora Hospital” means:

- (a) a hospital operated by Te Whatu Ora;
- (b) an associated health service that is provided by Te Whatu Ora; or
- (c) a programme operated by, or function within, Te Whatu Ora under or for which Te Whatu Ora procures medical devices; and

“UNSPSC” means the United Nations Standard Products and Services Code.

56. Interpretation

In this Agreement, unless the context requires otherwise:

- (a) references to clauses and schedules are to clauses and schedules of this Agreement;
- (b) the headings to clauses will be ignored in construing this Agreement;
- (c) the plural includes the singular and vice versa;
- (d) references to a gender include each other gender;
- (e) a statute includes that statute as amended from time to time and any regulations;
- (f) orders in council and other instruments issued or made under that statute from time to time and legislation passed in substitution for that statute;
- (g) an obligation not to do anything includes an obligation not to suffer, permit or cause that thing to be done;
- (h) derivatives of any defined word or term have a corresponding meaning;
- (i) all references to dollars are references to New Zealand dollars unless provided otherwise;
- (j) “including” and similar words do not imply any limitation; and
- (k) none of the terms are to be construed against a party by reason of the fact that that term was first proposed or was drafted by that party.

PART 8: Special terms

[Drafting Note:

The below provisions are intended as placeholders to insert a 'supplier specific' clause within the Part 8 structure. The Medical Device Listing Agreement Precedent Bank in the RFPs and Contracts Folder on Objective ("Precedent Bank") contains legally reviewed wording for clauses that should be used for drafting the Agreement.

In the event a placeholder, which is stated below, applies to a particular Category of Medical Device only and it is not appropriate to include a 'supplier specific' clause in Part 8, please include the clause in Part 9 under the relevant Category of Medical Device. This is particularly relevant for Additional warranties where placeholders have been included in Part 8 and 9.

In the event a placeholder is not relevant to the Agreement please delete it. The listed placeholders are not extensive and complex negotiations may require additional clauses to be included in Part 8.]

1. Additional definitions

In this Agreement, unless the context otherwise requires:

2. Medical Device queries

3. General obligations and warranties

3.1 Health System Catalogue

3.2 WAND Not Applicable Medical Devices

3.1 [Additional warranties]

3.2 Quality standards and special obligations for electrical Medical Devices

3.3 Maintenance and management services

3.4 Spare parts, software and updates

3.5 Special obligations

4. Ordering and delivering Medical Devices

4.1 Indent Items

5. **Supply obligations and Failure to Supply**

6. **Software**

7. **Confidential information**

PART 9: Special terms for each Category of Medical Device

[Drafting Note:

The below provisions are intended as placeholders to insert a 'category specific' clause within the Part 9 structure. The Precedent Bank contains legally reviewed wording for clauses that should be used for drafting the Agreement.

In the event a placeholder is not relevant to the Agreement please delete it. The listed placeholders are not extensive and complex negotiations may require additional clauses to be included in Part 9.]

1. Special terms for the [insert name of category e.g. wound care] Category of Medical Device

1.1 Additional definitions for the [] Category of Medical Device

In Part 9, clause 1 [and Annexure 1] of this Agreement, unless the context otherwise requires, for the [] Category of Medical Devices:

1.2 Price review for the [] Category of Medical Device

1.3 [Pricing structures] for the [] Category of Medical Device

1.4 Secondary Procurement for the [] Category of Medical Device

1.5 Ordering and delivering Medical Devices in the [] Category

1.6 Minimum shelf life for Medical Devices in the [] Category

1.7 Installation, commissioning and acceptance of Medical Devices in the [Category of Medical Device] Category

1.8 [Additional warranties for Medical Devices in the [] Category]

1.9 Maintenance services for the [Category of Medical Device] Category of Medical Device

1.10 Supply obligations and Failure to Supply for Medical Devices in the [Category of Medical Device]

1.11 Decommissioning and disposal for Medical Devices in the [Category of Medical Device]

1.12 Delisting for the [Category of Medical Device] Category of Medical Device

SCHEDULE 1: Medical Devices to be listed or to have listings amended

The Medical Devices supplied by you to Te Whatu Ora Hospitals or Logistics Providers (if applicable) under this Agreement are those as set out and described in the [Excel spreadsheet] OR [spreadsheet document entitled "[]"] annexed to this Agreement.

SCHEDULE 2: Product Specifications for any Medical Device

None.

SCHEDULE 3: Performance Standards and Reporting

1. Performance Standards

1.1 Key Performance Indicators

(a) You agree that you will meet the Key Performance Indicators (KPIs) listed below:

Subject	KPI or Report	Reference		Unit	KPI Formula and/or Reporting Requirements	Satisfactory Performance
		Section	Clause			
Assured Supply	Failure to Supply Incidents	Part 6	27.1(a)	Number	Number of Failure to Supply incidents & reasons	
				Days	Duration of each	
				%	$\frac{\text{Number of Failure to Supply incidents notified to PHARMAC}}{\text{Total number of Failure to Supply incidents}} \times 100$	
	Potential Failure to Supply	Part 6	27.1(a)	Number	Number of potential Failure to Supply incidents & reasons	
				Days	Duration of each	
				%	$\frac{\text{Number of potential Failure to Supply incidents notified to PHARMAC}}{\text{Total number of potential Failure to Supply incidents}} \times 100$	
	Delivery On-Time, In-full & In-Specification	Part 3	16	Number	Number of Purchase Order lines not delivered on time, in full and in spec	
				%	$\frac{\text{Number of Purchase Order lines delivered on time, in full & in spec}}{\text{Total number of Purchase Order lines delivered}} \times 100$	95%
				Days	Average number of days items were delivered after the contracted date	
Quality	Rejected on Arrival	Part 6	27.3(b)	Number	Number of Medical Devices rejected with reasons	
				%	$\frac{\text{Number of Medical Devices not rejected by DHBS}}{\text{Total number of Medical Devices shipped}} \times 100$	98%
	Reported Quality Issues	N/A	N/A	Number	Number of quality, manufacturing or performance issues received for the Medical Devices	

Customer Service	Complaints & Escalations	N/A	N/A	Number	Number of complaints received or escalations raised and a summary of the types of complaints	
				%	$\frac{\text{Number of complaints or escalations closed \& resolved within 14 days}}{\text{Total number of complaints or escalations}} \times 100$	80%
Communications	Change Management	Part 7	50	Yes/No	All amendments were notified and agreed in writing in accordance with Pharmac's current processes	Yes
	Quarterly Reporting	Part 5	24	Yes/No	Reports were complete and submitted on time	Yes

- (b) Pharmac may amend the KPIs stated in paragraph (a) above from time to time, provided that Pharmac consults with you prior to any amendment to the KPIs becoming effective.

2. Assessment against Performance Standards and outcomes of assessment

- (a) Pharmac will periodically assess your performance against the Performance Standards following receipt of a KPI Report, which Pharmac may verify with Te Whatu Ora Hospitals and Logistics Providers (as applicable).
- (b) Without limiting Pharmac's other rights under this Agreement or generally at law, the following interventions will be available to Pharmac in the event that you are not meeting any of the required Performance Standards:
- (i) give notice to remedy;
 - (ii) request further guarantees to remedy supply chain issues; and
 - (iii) give notice of withdrawal of Medical Devices from the Pharmaceutical Schedule due to continuous and/or ongoing product failure notifications.
- (c) Without limiting Pharmac's other rights under this Agreement or generally at law, Pharmac shall be entitled to utilise any of the interventions described in (b) that it considers necessary to manage unsatisfactory performance by you. The intervention that Pharmac utilises may depend on

the seriousness of the non-performance and the extent to which non-performance has been recurring. Pharmac may also utilise more than one of the interventions in (b) in respect of the same non-performance, including where an intervention has been used by Pharmac but has not resulted in a substantial enough improvement in your performance against the Performance Standards.

3. Sales Report

- (a) Each Sales Report provided pursuant to clause 24.2 is to be provided in Microsoft Excel format and is to include details of:
 - (i) the Supplier Product Code for each Medical Device;
 - (ii) a description of each Medical Device;
 - (iii) the Supplier Unit of Measure for each Medical Device;
 - (iv) the Quantity per Supplier Unit of Measure for each Medical Device;
 - (v) each Te Whatu Ora Hospital or Logistics Provider (as applicable) that purchased the Medical Device on behalf of a Te Whatu Ora Hospital;
 - (vi) the number of Supplier Units of Measure of each Medical Device supplied to each Te Whatu Ora Hospital or Logistics Providers (as applicable);
 - (vii) in respect of Medical Devices, the date on which the Purchase Order(s) were dispatched by you, or in respect of Consignment Medical Devices, the date of any invoice;
 - (viii) the actual price (exclusive of GST) at which the Te Whatu Ora Hospital or Logistics Provider (as applicable) was invoiced by you for each Supplier Unit of Measure in accordance with paragraph (vii) above. In the event the actual price invoiced is different to the Price for the applicable Supplier Unit of Measure of a Medical Device referenced in Schedule 1, you must provide Pharmac with reasons for the different price;
 - (ix) the Code (GTIN) as defined in Part 2, clause 7.1 (j) for each Medical Device (if available); and
 - (x) any other data as reasonably requested by Pharmac in writing to you on two weeks' notice before a Sales Report is due.
- (b) Pharmac may amend the requirements in (a) above from time to time and will advise you of any such amendment in writing and with reasonable notice before a Sales Report is due.

4. Supply Issues Report

- (a) Each Supply Issues Report provided to Pharmac pursuant to clause 24.3 must include the requisite details as specified in (b) below in respect of:
 - (i) any Low Risk Failure to Supply or potential Failure to Supply incidents that have been or are in the process of being resolved between you and Te Whatu Ora, Te Whatu Ora Hospitals and/or Logistics Providers (as applicable) in accordance with clause 27.1(b); and
 - (ii) any Failure to Supply or potential Failure to Supply incidents that you have already notified Pharmac of in accordance with clause 27.1.
- (b) The details that must be provided in each Supply Issues Report in respect of each incident of a type described in (a) above are:
 - (i) the Supplier Product Code;
 - (ii) description of each Medical Device;
 - (iii) the average usage per month over the previous 12-month period (or such shorter period as applicable where the relevant Medical Device has been listed on the Pharmaceutical Schedule for less than 12 months);
 - (iv) the quantity of stock remaining in your possession or under your control in New Zealand;
 - (v) the reason for the Failure to Supply or potential Failure to Supply issue (the **issue**);
 - (vi) whether the issue is Low Risk and, if not, the date that the issue was notified to Pharmac;
 - (vii) when the issue occurred;
 - (viii) when the issue was resolved or, if the issue is ongoing, when you expect it to be resolved;
 - (ix) the number and name of the Te Whatu Ora Hospitals affected by the issue;
 - (x) the delivery date for the next Purchase Order of the relevant Medical Device (if applicable);
 - (xi) details of any Alternative Medical Device that has been, or will be, supplied; and

- (xii) any other data or information as subsequently requested by Pharmac and as agreed by you (such agreement not to be unreasonably withheld or delayed).
- (c) For the purposes of this Agreement, “**Low Risk**” Failure to Supply or potential Failure to Supply situations are those where:
 - (i) the Te Whatu Ora Hospital(s) advises you that the situation does not result in significant disruption to the Te Whatu Ora Hospital(s) and any required Alternative Medical Devices are sourced by you and provided to Te Whatu Ora Hospital(s) in a clinically appropriate timeframe, as determined by the Te Whatu Ora Hospital(s); or
 - (ii) Pharmac has notified you in writing that the situation is Low Risk.
- (d) Where you cannot reasonably decide whether a certain situation is Low Risk you must notify Pharmac of the Failure to Supply or potential Failure to Supply.
- (e) Pharmac may amend the requirements in (b) above from time to time and will advise you of any such amendment in writing and with reasonable notice before a Supply Issues Report is due.

SCHEDULE 4: Supplier contact numbers

1. **Liaison person(s)**

2. **Medical Device queries contact number**

3. **Contract Manager – [supplier]**

4. **Contract Manager – Pharmac**

[ANNEXURE 1: Service and Maintenance Schedule]

[Drafting Note:

Only included if there are service and maintenance costs associated with the Medical Devices included in the Agreement.]