PHARMAC
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[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 New Zealand Public Health and Disability Act 2000;

- "**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 DHB Hospitals, 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 DHB 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).

Parts

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

- Part 1: the role of Pharmac and the DHB 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 DHB Hospital's discretion, its required delivery point and the price at which that Medical Device can be procured by DHB 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 DHB Hospitals

1. Pharmac's Role

1.1 Overview of Pharmac's role

(a) In accordance with the New Zealand Public Health and Disability Act 2000, 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 District Health Boards, 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 DHB Hospitals. As such, your contractual relationship is with Pharmac even though your supply of Medical Devices is ultimately for the benefit of DHB Hospitals, 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 New Zealand Public Health and Disability Act 2000;

(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 DHB 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 DHB Hospital and Logistics Provider) on service initiatives and in providing market information to ensure that the DHB 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 DHB Hospitals

(a) The DHB 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 DHB Hospital (as notified by each DHB 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 DHB Hospitals as set out in this Agreement).

3. Logistics Provider

(a) A DHB 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 DHB 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 DHB 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 DHB 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 DHB 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 DHB 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 DHB 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 DHB Hospital.

(c) The support described in (a) will be provided at no cost to the DHB 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 DHB 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, a DHB, or the agent of a DHB(s) 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 DHB 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 DHB 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 DHB 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 DHB 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 DHB Hospital or Logistics Provider (as applicable) will meet all reasonable costs, provided that these costs have been notified to the DHB Hospital or Logistics Provider (as applicable) in advance) for supply to DHB 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 DHB Hospitals 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 DHB 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 DHB Hospital.

(b) If you have an agreement with the relevant DHB 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 DHB Hospital does not use that Medical Device before its expiry or use-by date, you agree to allow that DHB Hospital to return that Medical Device to you and to provide that DHB Hospital with a refund for that Medical Device.

(c) This clause confers a benefit on (and is enforceable by) DHB 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 DHB 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 DHB 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 DHB 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 DHB Hospital.

9.8 Training and Education about Medical Devices

(a) You will provide, at no cost to the DHB Hospitals, at a time or times agreed between you and the relevant DHB 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 DHB 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 DHB 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 DHB 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 DHB 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 DHB Hospital.

(d) The training and education services shall be of a standard acceptable to the relevant DHB Hospital (acting reasonably) such that they provide to the DHB 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. DHB 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 DHB Hospital and other contractors (if any) engaged by the DHB 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 DHB 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 DHB 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 DHB Hospital or to stipulate that the training and education services will be provided by a specific member of your Personnel. Where the relevant DHB 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 DHB 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 DHB Hospital.

(k) Upon the completion of the training and education services you will leave the relevant DHB Hospital's sites in a clean and tidy state for use and occupation by the DHB Hospital.

(l) You must return all property, used for the provision of training and education services, belonging to the relevant DHB Hospital in a satisfactory condition and co-operate and hand to the relevant DHB Hospital all copies of files, documents, data and information held by you.

9.9 Training and education materials

(a) You will provide, each DHB Hospital with:

(i) brochures and clinical aids to support the DHB 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 DHB 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 DHB 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 DHB 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 DHB Hospital, airfares and on location costs (including local travel expenses to and from the course venue, accommodation and reasonable living expenses) in respect of DHB 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 DHB 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 DHB 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 DHB 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 DHB 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 DHB 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 DHB Hospital or Logistics Provider submits a request in writing via email or facsimile either in the DHB Hospital's, Logistics Provider's or your standard Purchase Order form, or through some other written format;

(ii) the relevant DHB Hospital or Logistics Provider places an order over the phone with you, which you capture in writing in the DHB Hospital's, Logistics Provider's or your standard Purchase Order form, or through some other written format and send to the DHB Hospital or Logistics Provider for confirmation prior to supply;

(iii) the relevant DHB 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 DHB 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 DHB 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 DHB Hospital or Logistics Provider (as applicable) will not be required to pay for any Medical Devices delivered to the DHB 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 DHB 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 DHB Hospital's or Logistics Provider's reasonable costs of returning the Medical Devices to you (along with any costs that the DHB Hospital or Logistics Provider incurs in respect of collecting the Medical Devices to return to you, if applicable) upon receiving written notice from the DHB Hospital or the Logistics Provider of the costs incurred.

15. Consignment stock

(a) You may supply Consignment Medical Devices to DHB Hospitals on the following terms:

(i) you may only supply a Consignment Medical Device to a DHB Hospital with the written approval of the DHB Hospital and, where Pharmac gives notice to you that its approval is also required to supply a Consignment Medical Device to a DHB Hospital, of Pharmac;

(ii) you may only place such quantities of Consignment Medical Devices in a DHB Hospital on consignment up to the limits agreed with the DHB Hospital for each Medical Device. Pharmac may at any time require such limits to be reduced by giving written notice to the relevant DHB Hospital and to you, following consultation with the relevant DHB Hospital;

(iii) for each separate DHB Hospital you must retain a record of:

(A) the total number of each Consignment Medical Device you have placed at that DHB Hospital and which have not been used by the DHB Hospital at any one time;

(B) the number of each Consignment Medical Device you replenish at the DHB Hospital;

(C) the dates that you replenish each Consignment Medical Device in (B),

and you must make this information immediately available to the relevant DHB Hospital and to Pharmac upon a request being made by the DHB 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 DHB 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 DHB Hospital at the point of use by the DHB Hospital;

(v) expired Consignment Medical Devices will be replaced by you with no charge to the DHB Hospital;

(vi) you will notify the DHB Hospital of any damaged Consignment Medical Devices or Consignment Medical Devices out of their original packaging. The DHB 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 DHB 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 DHB Hospital and must only occur on such dates and times and frequencies and to such locations as the DHB Hospital agrees. The

DHB Hospital may request that you postpone a planned delivery of Consignment Medical Devices until a later date that is convenient for the DHB 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 DHB 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 DHB Hospital (at times to be agreed with each DHB Hospital). The results of the stock-take must be provided to the DHB 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 DHB 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 DHB 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 DHB Hospital shall ensure that the exterior packaging of the Consignment Medical Devices is not written on or marked in any manner by DHB Hospital Personnel.

(g) The DHB Hospital shall store Consignment Medical Devices at a location ("**Storage Area")** which is agreed between the DHB Hospital and you.

(h) The DHB 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 DHB Hospital).

(i) The DHB 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 DHB Hospital, as and where required.

(j) The DHB 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 DHB 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 DHB 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 DHB 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 DHB Hospital) by DHB Hospital Personnel,

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

(m) You may, with the prior approval of a DHB Hospital, add or remove Consignment Medical Devices from the DHB Hospital's consignment inventory upon one (1) business days' notice. For each stock transfer, you must notify the DHB 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 DHB 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 DHB Hospital or the Logistics Provider (as applicable). A delivery note, in accordance with the DHB Hospital's or Logistics Provider's requirements, stating the DHB 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 DHB 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 DHB 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 DHB 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 DHB 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 DHB Hospital or Logistics Provider a reasonable urgent delivery fee, provided this has been notified to the DHB 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 DHB Hospital or Logistics Provider (as applicable).

(g) The DHB 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 DHB Hospital), as applicable.

(h) The DHB 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 DHB 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 DHB 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 DHB 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 DHB 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 DHB Hospital or Logistics Provider. If a DHB 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 DHB 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 DHB 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 DHB Hospital or Logistics Provider (as applicable) in advance and the DHB 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 DHB 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 DHB 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 DHB 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 DHB 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 DHB Hospitals or Logistics Providers under this Agreement. All information provided by Pharmac or any DHB 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 DHB 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 DHB 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 DHB 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 DHB Hospital or Logistics Provider (as applicable) may return (at the DHB Hospital's or Logistics Provider's cost) any quantity of Medical Devices, provided the DHB 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 DHB Hospital or Logistics Provider gives notice under (a), the Medical Devices must either be returned by the DHB Hospital or Logistics Provider to you or arrangements must have been made with you for you to collect the Medical Devices from the DHB Hospital or Logistics Provider, within ten (10) business days of the date of delivery of those Medical Devices.

(c) In the event that the DHB 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 DHB 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 DHB 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 DHB Hospital or Logistics Provider has already paid for the Medical Devices that it wishes to return.

(d) Notwithstanding (c), where a DHB Hospital or Logistics Provider returns any Medical Devices pursuant to (a), you may invoice the DHB 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 DHB 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 DHB Hospital or Logistics Provider (or helping to facilitate this for

the DHB 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 DHB Hospital or Logistics Provider under (d), unless otherwise agreed to by Pharmac in writing, you must not charge a DHB Hospital or Logistics Provider any additional fees in relation to the return of Medical Devices.

20. DHB Hospital or Logistics Provider sites

20.1 General

(a) In performing your obligations under this Agreement you shall comply with any DHB Hospital policies, which have been notified to you.

(b) You acknowledge that:

(i) a DHB 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 DHB Hospital's site or to any DHB Hospital's property or to any person lawfully on any DHB Hospital's sites will be made good by you at your expense.

(c) You will respect the privacy of patients of DHB 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 DHB 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 DHB 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 DHB 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 DHBs, 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 DHBs, Logistics Providers and Pharmac to ensure compliance with those duties.

(d) You must inform Pharmac and the relevant DHB 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 DHB 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 DHB Hospital or Logistics Provider may deny access to any DHB 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 DHB 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 DHB 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 DHB 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 DHB 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 DHB 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 DHB Hospital's or Logistics Provider's (as applicable) obligation to make the relevant payment and the DHB 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 DHB 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 DHB Hospital or, if applicable, a Logistics Provider in connection with any payment by that DHB Hospital or Logistics Provider (as applicable) to you, then that DHB 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 DHB 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 DHB Hospital is to be offered a lower price

Notwithstanding clause 9.1(b), you may supply a Medical Device to a DHB 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 DHB Hospital, and every Logistics Provider of the reduced Price of the Medical Device;

(b) notify Pharmac, every DHB 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 DHB 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 DHB Hospital placing the Purchase Order

(a) Where a Purchase Order has been received from a DHB Hospital or where a DHB Hospital has used a Consignment Medical Device you are to invoice the particular DHB 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 DHB Hospital);

(ii) the particular DHB Hospital's Purchase Order reference number (also required for Consignment Medical Devices unless otherwise agreed with the individual DHB Hospital);

(iii) the net amount payable in respect of the Medical Device supplied to that DHB Hospital in accordance with this Agreement;

(iv) full details in respect of the Medical Device supplied to that DHB 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 DHB 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 DHB 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 DHB 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 DHB 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 DHB Hospital's or Logistics Provider's failure to dispute any invoice prior to payment does not prejudice that DHB 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 DHB Hospital or Logistics Provider (as applicable) may withhold, deduct or set off the amount of any overpayment or any amount recoverable by that DHB 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 DHB Hospital or Logistics Provider on account of another DHB 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) DHB 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 DHB 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 DHB 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 DHB Hospital or Logistics Provider may provide Pharmac and its agents with any price and volume data held by that DHB 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 DHB 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 DHB 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 DHB 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 DHB Hospital or Pharmac, you must provide the requesting DHB Hospital or Pharmac with either:

(i) a copy of your current Business Continuity Plan; or

(ii) provide written assurances to Pharmac's or the DHB 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 DHB 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 DHB 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 DHB 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 DHB 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 DHB 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 DHB 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 DHB Hospital (or a Logistics Provider, if applicable), then:

(i) you must use your best endeavours to source, within what the relevant DHB Hospital (or Logistics Provider, if applicable) considers to be a reasonable period of time, an Alternative Medical Device for supply to any DHB 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 DHB Hospitals (and/or Logistics Provider(s), if applicable) any additional costs incurred by such DHB 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 DHB Hospitals (and/or Logistics Provider(s), if applicable) any additional costs incurred by such DHB 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 DHB 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 the relevant DHB'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 DHB Hospital, you will rectify any defects associated with the Medical Devices at no extra cost to Pharmac or the DHB 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 DHB Hospital or Logistics Provider (as applicable). Any Medical Device rejected by the DHB Hospital or Logistics Provider (as applicable) will, upon demand, be returned to you at your risk and expense. You are required to pay the DHB Hospital's or Logistics Provider's reasonable costs of returning the Medical Devices to you (along with any costs that the DHB Hospital or Logistics Provider incurs in respect of collecting the Medical Devices to return to you, if applicable) upon receiving written notice from the DHB 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 DHB Hospital or Logistics Provider (as applicable) reserves its right to procure alternative products elsewhere if the DHB 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 DHB Hospital or Logistics Provider (as applicable) all money paid by the DHB 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 DHB Hospital or Logistics Provider), unless you have provided an Alternative Medical Device to the satisfaction of the DHB Hospital or Logistics Provider (as applicable). That refund will be recoverable from you as a debt due to the DHB Hospital or Logistics Provider (as applicable); and

(b) without prejudice to any other remedies which it may have, the DHB 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 DHB 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 DHB Hospital or Logistics Provider (as applicable) by you on demand and will be recoverable from you as a debt due to the DHB Hospital or Logistics Provider (as applicable).

28.2 Indemnity for Failure to Supply

(a) Subject to (b) below, you agree to indemnify the DHB 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 DHB 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 DHB 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 DHB Hospitals) liquidated damages for the administrative and/or operational costs incurred by Pharmac and DHB 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 DHB 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 DHB 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) DHB 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 DHB 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 do not agree on a dispute resolution technique within fourteen (14) days after the date notice of a dispute was given, the dispute is to be mediated according to the standard mediation agreement of the Resolution Institute, and the chief executive of the Resolution Institute (or their nominee) will select the mediator and determine the mediator's remuneration;

(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.

(b) For the avoidance of doubt you acknowledge and agree that Pharmac may elect to involve any relevant District Health Board, 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 DHB 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 DHB 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 DHB Hospital, Logistics Provider or Pharmac and that the relevant DHB Hospital or Logistics Provider is solely responsible for its obligations in respect of the Medical Devices and any associated services supplied to that DHB Hospital or Logistics Provider under this Agreement. No DHB 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 DHB Hospital or Logistics Provider in connection with this Agreement.

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

(a) You indemnify each DHB 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 DHB 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 DHB Hospital, Logistics Provider and Pharmac from and against all damages, losses, liability, costs and expenses, including legal fees, incurred by the DHB 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 DHB 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 DHB 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 and DHB 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's 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 each District Health Board is a Crown entity under the Crown Entities Act 2004. It is therefore essential that you always act in your dealings with the DHB 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 DHB Hospitals' probity and any other policy documents relating to sponsorship, gifts, hospitality, inducements or similar, such as declaration, authorisation and probity register requirements. The DHB Hospital will provide you with a copy of its relevant policy documents on request; and

(ii) provide DHB 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 DHB Hospitals; and

(b) supersedes and extinguishes all prior agreements and understandings between us, and between you and any District Health Board regarding supply of each Medical Device to DHB Hospitals.

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 DHB Hospitals and related persons (including, where relevant, a Logistics Provider), and are enforceable at the suit of any such DHB Hospitals or 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 DHB Hospital and each Logistics Provider (if applicable) do not end. 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 DHB 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 DHB 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;

"DHB Hospital" means a DHB's hospital and/or an associated health service that is provided by a DHB and for which that DHB procures medical devices;

"District Health Board" (or **"DHB"**) has the same meaning as in the New Zealand Public Health and Disability Act 2000;

"**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 an event that is beyond the reasonable control of the party immediately affected by the event. A Force Majeure Event does not include any risk or

event that the party claiming could have prevented or overcome by taking reasonable care, including by managing such risk in any sub-contracting arrangements. Examples include:

(a) acts of God, lightning strikes, earthquakes, tsunamis, volcanic eruptions, floods, storms, explosions, fires, pandemics and any natural disaster;

(b) acts of war (whether declared or not), invasion, actions of foreign enemies, military mobilisation, requisition or embargo;

(c) acts of public enemies, terrorism, riots, civil commotion, malicious damage, sabotage, rebellion, insurrection, revolution or military usurped power or civil war; or

(d) contamination by radioactivity from nuclear substances or germ warfare or other hazardous properties,

and for the avoidance of doubt:

(e) any failure on the part of a person in the relevant Medical Device supply chain; or

(f) any act or omission by a related entity or sub-contractor of yours,

is not considered by Pharmac to constitute a Force Majeure Event;

"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 DHB 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 DHB Hospital to arrange the procurement of and/or take delivery of a Medical Device required by the DHB 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 established under the New Zealand Public Health and Disability Act 2000;

"Pharmaceutical Schedule" means the pharmaceutical schedule produced by Pharmac pursuant to section 48(a) of the New Zealand Public Health and Disability Act 2000;

"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 DHB Hospital's discretion, the DHB 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; 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; and

(j) “including” and similar words do not imply any limitation.

PART 8: Special terms

PART 9: Special terms for the Permanent Coronary Drug-Eluting Stent Sub-category

1. Additional definitions

In this Agreement, unless the context otherwise requires:

Alternative Brand Allowance means the alternative brand allowance relating to the Medical Device in the DES Sub-category, as indicated as a percentage amount of the Total Medical Device Volume, in the column entitled "ABA Limit" in the table set out in Part 9, clause 2.1(d);

Brand Allowance Indicator means the actual percentage of Brand Allowance Medical Devices purchased by DHB Hospitals relative to the Total Medical Device Volume in a Relevant Period;

Brand Allowance Medical Devices means an alternative supplier's brand of the Medical Device in the DES Sub-category. For the avoidance of doubt, a Brand Allowance Medical Device shall not be interpreted to be an Alternative Medical Device for the purposes of the Agreement;

Brand Compensation means the compensation payable to you in accordance with Part 9, clause 2.3(c);

Brand Differential means the difference between the Brand Allowance Indicator and the Alternative Brand Allowance;

"DES Sub-category" means a grouping of medical devices with the scope of the Permanent Coronary Drug-Eluting Stent Sub-category defined in Schedule 2;

Eligible Volume means the Volume Multiplier multiplied by the Brand Differential, being a volume of Medical Devices in the DES Sub-category eligible for Brand Compensation in Units of that Medical Device;

End Date means the last day of the Principal Supply Period;

Principal Supplier means you, being the principal supplier of the relevant Medical Device in the DES Sub-category to DHB Hospitals (subject to the Alternative Brand Allowance provisions);

Principal Supply Period means the period beginning on the day after the expiry of the Transition Period and ending on [ ];

Principal Supply Status means the status of being the Principal Supplier to DHB Hospitals of the Medical Device in the DES Sub-category for the Principal Supply Period;

Relevant Period means the period commencing on [ ] and ending on [ ]:

Total Brand Allowance Medical Device Volume means the total volume of Brand Allowance Medical Devices in the DES Sub-category purchased by DHB Hospitals in a Relevant Period, specified in Units of that Medical Device;

Total Medical Device Volume means the total volume of Medical Devices in the DES Sub-category (inclusive of Brand Allowance Medical Devices) purchased by DHB Hospitals in a Relevant Period, specified in Units of that Medical Device;

Transition Period means, the [ ] month period commencing on the date on which the listing of the Medical Devices in the DES Sub-category pursuant to this Agreement takes effect;

Unit means an individual unit of a Medical Device (e.g. a permanent coronary drug-eluting stent); and

Volume Multiplier means the Total Medical Device Volume divided by one hundred (100) (which shall equate to 1% of the Total Medical Device Volume), specified in Units of that Medical Device.

2. Market Share

2.1 Principal Supplier

(a) You shall have Principal Supply Status during the Principal Supply Period, which shall be subject to the Alternative Brand Allowance, where other supplier brands of the Medical Device may be purchased by DHB Hospitals.

(b) The Alternative Brand Allowance referred to in paragraph (a) above is specified as a percentage of the Total Medical Device Volume for the Medical Device, that percentage being as set out in paragraph (d) below.

(c) You acknowledge and agree that any other supplier brands of the Medical Device may be concurrently listed on the Pharmaceutical Schedule at any time during the Transition Period and Principal Supply Period and your rights under this Agreement do not extend to an exclusive listing of the Medical Device on the Pharmaceutical Schedule.

(d) The Alternative Brand Allowance relating to the Medical Device, as indicated as a percentage amount of the Total Medical Device Volume, is set out in the column entitled "ABA Limit" in the table below:

Medical Device	ABA Limit
[ ]	[ ]

2.2 Exceptions to Principal Supply Status

(a) Pharmac may, from time to time during the Principal Supply Period or the Transition Period, amend the Alternative Brand Allowance for the Medical Device after consultation with a relevant medical adviser (being either the Ministry of Health, PTAC or its sub-committees), provided that Pharmac may only increase the Alternative Brand Allowance without your prior agreement if it has a direction to that effect from the Ministry of Health or its successor, or a recommendation that it do so from PTAC or its sub-committees, based on a significant clinical issue.

(b) Subject to clause 2.3 below, you acknowledge and agree that while you have Principal Supply Status in respect of the DES Sub-category:

(i) other supplier brands of the Medical Device may be purchased by DHB Hospitals, subject to the Alternative Brand Allowance;

(ii) without derogating from any other rights available to Pharmac or DHB Hospitals under this Agreement or otherwise, if you fail to supply the Medical Device in

accordance with this Agreement (other than for a reason that Pharmac reasonably considers, following discussion with you, to be wholly outside your control) at any time during the Principal Supply Period, then the Alternative Brand Allowance shall not apply and other supplier brands of the Medical Device may be purchased by DHB Hospitals without limitation during that period of non-supply and any calculation performed in accordance with clause 2.3 below shall exclude that period of non-supply; and

(iii) purchases made, or medical devices used, by DHB Hospitals in the following circumstances will be excluded from any calculations carried out in accordance with clause 2.3 below:

(A) medical devices used for the purposes of trialling in accordance with clause 3 below; and

(B) medical devices provided to DHB Hospitals in accordance with the supplier's obligations in relation to emergency and disaster supply, as contained in Part 2, clause 9.2.

2.3 Principal Supply Status Monitoring

(a) If you reasonably believe that the usage of other supplier brands of the Medical Devices purchased by DHB Hospitals exceeds the Alternative Brand Allowance for a particular Medical Device during the Principal Supply Period, you may at any date after a three (3) month period following the end of any Relevant Period, request that Pharmac carry out calculations for that Relevant Period in accordance with the procedure set out in this clause 2.3, and Pharmac may, acting reasonably, agree to carry out such calculations, provided that if Pharmac refuses to carry out such calculations, it will provide you with the reasons for refusing to do so.

(b) Within 30 business days of Pharmac accepting your request to carry out calculations in accordance with paragraph (a) above, Pharmac shall carry out the following calculations for the Relevant Period in question:

(i) (Total Brand Allowance Medical Device Volume / Total Medical Device Volume) x 100 = Brand Allowance Indicator;

(ii) Brand Allowance Indicator – Alternative Brand Allowance = Brand Differential

(c) In the event the Brand Differential is a number greater than zero i.e. a positive amount, Pharmac shall carry out the following calculations for the Relevant Period in question:

(i) Total Medical Device Volume / 100 = Volume Multiplier;

(ii) Volume Multiplier x Brand Differential = Eligible Volume;

(iii) (Eligible Volume x Price) / 3 = Brand Compensation

(d) Pharmac will notify you in writing of any Brand Compensation payable or not in accordance with paragraphs (b) and (c) above and will provide you with the details of the relevant party or parties to be invoiced for any Brand Compensation payable. Following such notification to you from Pharmac, you may invoice the relevant party or parties for the Brand Compensation.

(e) You acknowledge and agree that the data extracted from the records used by Pharmac are the best data and those records are the best records, for the purposes of carrying out the calculations.

(f) You may, within 10 business days following notification of the outcome of the calculations in accordance with paragraph (d) above (the "**Calculation**"), notify Pharmac in writing that you dispute the particular Calculation and that you require an audit of that Calculation to be carried out. If you do give a notice to Pharmac under this clause within that 10-business day period, then the following provisions are to apply:

(i) The audit is to be carried out by an independent person jointly approved by us or, if there is no agreement on a mutually acceptable person within 5 business days of the date of your notice under this clause, then by an independent person nominated for that purpose by the President for the time being of the New Zealand Institute of Chartered Accountants.

(ii) The independent person is to audit the particular Calculation, which is disputed by you, based on all relevant electronic data which is extracted by Pharmac from the records maintained by it.

(iii) In carrying out the audit, the independent person is to be considered as acting as an expert and not as an arbitrator.

(iv) The independent person will be required to complete the audit, and to provide us with a written determination in that regard, within 5 business days of receiving all the information required by the independent person to make a determination and, in any case, no later than 10 business days from the date of his or her acceptance of appointment or nomination under this clause, unless we agree otherwise. The independent person's determination of the particular Calculation is to be final and binding on both of us.

(v) The costs incurred by the independent person in completing the audit are to be met by you, irrespective of the outcome of the audit.

2.4 Withdrawal of Principal Supply Status

(a) Pharmac may withdraw Principal Supply Status in relation to your supply of the Medical Device in the DES Sub-category (in which case clauses 2.1 and 2.3 of this Part 9 will no longer apply), by written notice to you at any time during the Principal Supply Period or (in anticipation) during the Transition Period if:

(i) you increase the price of the Medical Device in the DES Sub-category above the relevant price set out in Schedule 1;

(ii) there is a Failure to Supply the Medical Device in the DES Sub-category in accordance with this Agreement; or

(iii) any Permit (if applicable) for the Medical Device in the DES Sub-category is withdrawn.

(b) Any withdrawal of Principal Supply Status is without prejudice to Pharmac's rights under this Agreement and, for the avoidance of doubt, does not affect your obligation to supply the Medical Device in the DES Sub-category on the terms set out in, and in accordance with, this Agreement.

2.5 Suspension of Principal Supply Status

(a) If, at any time during the Principal Supply Period or (in anticipation) during the Transition Period, there is a Failure to Supply the Medical Device in the DES Sub-category in accordance with this Agreement, then Pharmac may suspend Principal

Supply Status in relation to your supply of the Medical Device in the DES Sub-category for the period of such inability.

(b) Any suspension of Principal Supply Status is without prejudice to Pharmac's rights under this Agreement and, for the avoidance of doubt, does not affect your obligation to supply the Medical Device in the DES Sub-category on the terms set out in, and in accordance with, this Agreement.

(c) Pharmac may, at any time, in its sole discretion, notify you of the date on which the suspension of Principal Supply Status under this clause 2.5 ceases and on which date:

(i) Principal Supply Status is to be re-implemented in respect of the Medical Device in the DES Sub-category; or

(ii) Principal Supply Status is to be withdrawn for the Medical Device in the DES Sub-category in accordance with clause 2.4.

2.6 Supply arrangements after the End Date

(a) Pharmac may, at its sole discretion, with effect from the End Date:

(i) require a Medical Device to continue to be the subject of a listing agreement, in which case Pharmac will give you written notice not less than three months prior to the End Date; or

(ii) apply any of the strategies under Pharmac's then current OPPs to the DES Sub-category (including delisting the Medical Devices in the DES Sub-category).

(b) If a Medical Device in the DES Sub-category is to continue to be the subject of a listing agreement between you and Pharmac, then:

(i) you will cease to have Principal Supply Status in respect of the Medical Device in the DES Sub-category; and

(ii) that Medical Device will otherwise remain listed subject to the terms of this Agreement, to the extent applicable, or on any such new terms as are agreed between us.

3. Clinical trials

3.1 Clinical trials of medical devices in the DES Sub-category

(a) The parties agree that nothing in this Agreement is intended to affect the common practice of suppliers supplying certain quantities of medical devices in the DES Sub-category to DHB Hospitals for the purpose of registered clinical trials.

(b) Any Alternative Medical Devices or Medical Devices provided to a DHB Hospital for the purpose of a registered clinical trial will be exempt from inclusion in the calculation of Brand Compensation as described in Part 9, clause 2.3 (c).

(c) Notwithstanding Part 2, clause 9.1, you may supply a Medical Device, for the purpose of a registered clinical trial, to a DHB Hospital at a Price that is less than the price listed or referenced in Schedule 1 provided that you obtain Pharmac's prior written agreement.

(d) You must provide Price and volume data to Pharmac for all Medical Devices provided to a DHB Hospital for the purpose of a registered clinical trial in accordance with Part 5, clause 24.2.

(e) For the avoidance of doubt this clause 3.1 does not apply to product evaluation testing by a DHB Hospital to test medical device acceptability with a view to changing medical device.

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

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

SCHEDULE 2: Product Specifications for any Medical Device

1.1 DES Sub-category scope

For the purposes of this Agreement, the DES Sub-category:

(a) includes:

(i) non-bioresorbable coronary stents coated with a pharmacological agent(s) known to suppress restenosis; but

(b) does not include:

(i) bio-resorbable stents;

(ii) bare metal stents;

(iii) non-coronary stents; and

(c) other medical devices determined by Pharmac to be out of scope of this Sub-category, following what Pharmac considers to be appropriate clinical consultation.

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	
				%	$\frac{Number\ of\ Failure\ to\ Supply\ incidents\ notified\ to\ PHARMAC}{Total\ number\ of\ Failure\ to\ Supply\ incidents} \times 100$	
	Potential Failure to Supply	Part 6	27.1(a)	Number	Number of potential Failure to Supply incidents & reasons	
				Days	Duration of each	
				%	$\frac{Number\ of\ potential\ Failure\ to\ Supply\ incidents\ notified\ to\ PHARMAC}{Total\ number\ of\ potential\ Failure\ to\ Supply\ incidents} \times 100$	
	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	
				%	$\frac{Number\ of\ Purchase\ Order\ lines\ delivered\ on\ time,in\ full\ \&\ in\ spec}{Total\ number\ of\ Purchase\ Order\ lines\ delivered} \times 100$	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	
				%	$\frac{Number\ of\ Medical\ Devices\ not\ rejected\ by\ DHBs}{Total\ number\ of\ Medical\ Devices\ shipped} \times 100$	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	
				%	$\frac{Number\ of\ complaints\ or\ escalations\ closed\ \&\ resolved\ within\ 14\ days}{Total\ number\ of\ complaints\ or\ escalations} \times 100$	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 DHB 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) the DHB that purchased the Medical Device or Logistics Provider (as applicable) that purchased the Medical Device on behalf of the DHB;

(vi) each DHB Hospital or Logistics Provider (as applicable) that purchased the Medical Device on behalf of a DHB Hospital;

(vii) the number of Supplier Units of Measure of each Medical Device supplied to each DHB Hospital or Logistics Providers (as applicable);

(viii) 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;

(ix) the actual price (exclusive of GST) at which the DHB 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;

(x) the Code (GTIN) as defined in Part 2, clause 7.1 (j) for each Medical Device (if available); and

(xi) 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 the relevant DHBs, DHB 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 DHBs 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 DHB Hospital(s) advises you that the situation does not result in significant disruption to the DHB Hospital(s) and any required Alternative Medical Devices are sourced by you and provided to DHB Hospital(s) in a clinically appropriate timeframe, as determined by the DHB 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