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) District Heath Boards may, and in the future will be required to, purchase Medical Devices listed on the Pharmaceutical Schedule at the Prices listed on the Pharmaceutical Schedule.

(d) 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.

(e) You acknowledge that given PHARMAC's role in relation to procuring and listing Medical Devices is new and will evolve over time, this Agreement may need to be amended following appropriate consultation as PHARMAC's role evolves, to ensure a consistent approach is adopted by PHARMAC to its procurement and listing of Medical Devices.

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 Part 8 of 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 one of the following three categories of medical device for the purpose of applying unique provisions under this Agreement to each category of medical device:

(i) Consumable or Durable Medical Device;

(ii) Capital Medical Device; or

(iii) Capital with Consumable Items Medical Device.

(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 the express written consent of PHARMAC, 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 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 in Schedule 1 and attached as Annexure 1 to Schedule 1, 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 Education services and additional services

Part 8 of this Agreement includes:

(a) any education services; and

(b) any additional services,

that you must provide in conjunction with the supply of a particular 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. Your initial nominated contract manager is named in Schedule 4. 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; and

(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.

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 purchased, and take delivery of Medical Devices purchased.

(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 purchase 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 purchased, and for taking delivery of Medical Devices.

(c) If a DHB Hospital utilises the services of a Logistics Provider to purchase 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.

(d) You acknowledge that the arrangements regarding the District Health Boards' use of Logistics Providers and the terms of those arrangements have not been finalised as at the date we have entered into this Agreement. Accordingly, you agree that PHARMAC may give notice to you at any stage that any delivery, payment, invoicing or other arrangements relevant to a Logistics Provider (including the entity responsible for paying an invoice) shall be different to what is set out in this Agreement. You agree to comply with any alternative arrangements as notified to you by PHARMAC in accordance with this paragraph (d).

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 purchasing, 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 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.

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 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; and

(ii) 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 other medical device advisory committee, based on patient safety.

PART 2: General obligations and warranties

7. General 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 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) be delivered free of any encumbrance, adverse interest or claim by any third party;

(f) have clear and indelibly inscribed labels in English;

(g) 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

(h) if requested by PHARMAC, a DHB, or the agent of a DHB(s) obtain a Global Trade Item Number (GTIN) and/or United Nations Standard Products and Services code (UNSPSC) ("**Code(s)**") that apply to the relevant Medical Device. In this event you will obtain the Code(s) within 6 (six) months and you will notify the requester of the Code(s) assigned.

8. Special warranties

(a) Schedule 2 sets out any additional warranties that are specific to the Category of Medical Device that the relevant Medical Device is set out under in Schedule 1.

(b) Part 8 sets out any additional warranties that are particular to a specific Medical Device.

(c) Part 8 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) Except as permitted in clause 22.5 of this Agreement, 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 medical devices that are the same brand as the 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 9.9, 27.1 and 28 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 or Schedule 2 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 ensure you are not in breach of any Intellectual Property Rights of any third party.

9.6 Stock holdings

(a) Part 8 or Schedule 2 of this Agreement will set out any minimum requirements 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.

(b) You must notify PHARMAC immediately once you become aware that the amount of stock of a Medical Device held in New Zealand reduces below the required level, as set out in Part 8 or Schedule 2.

9.7 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 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 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 credit for that Medical Device.

(c) This clause confers a benefit on (and is enforceable by) DHB Hospitals in accordance with the Contracts (Privity) Act 1982.

9.8 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.

(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 9.9, 27.1, and 28 below.

(c) On request of a DHB Hospital or PHARMAC, you must provide the requesting DHB Hospital or PHARMAC with a copy of your current Business Continuity Plan which must demonstrate the continuity arrangements you have in place with respect to the supply of all Medical Devices.

9.9 Notification of Potential Out-of-Stock Event and supply of Alternative Medical Device

(a) You must:

(i) notify PHARMAC in writing as soon as you have reasonable cause to believe that you will fail to supply a Medical Device in accordance with this Agreement;

(ii) where possible, notify PHARMAC and the relevant DHB Hospitals (or Logistics Provider(s), if applicable) if at any time a Potential Out-of-Stock Event occurs.

(b) If you fail to supply a Medical Device in accordance with this Agreement 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 procure, 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 procure 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 purchase 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 purchase of the Alternative Medical Device.

(c) This clause confers a benefit on (and is enforceable by) DHB Hospitals and Logistics Providers in accordance with the Contracts (Privity) Act 1982.

(d) This clause 9.9 applies in respect of all Consumable and Durable Medical Devices, and also applies unless expressly provided otherwise in Part 8 in respect of all Capital Medical Devices and Capital with Consumable Items Medical Devices.

9.10 Material Safety Data Sheets

You must make available to each DHB Hospital, in English, a current Material 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 Material 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.

10. Special obligations

(a) Schedule 2 sets out any additional obligations that are specific to the Category of Medical Device that the relevant Medical Device is set out under in Schedule 1.

(b) Part 8 sets out any additional obligations that are specific to a specific Medical Device.

11. Quality standards applying to listed Medical Devices

Part 8 sets out any quality standards that apply to a specific Medical Device and any relevant 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. Updates and upgrades in Medical Devices

13.1 Updates in Medical Devices

(a) You may make periodic updates to any Medical Device so long as that Medical Device continues to conform to the relevant Product Specification for that Medical Device and is approved by PHARMAC, such approval not to be unreasonably withheld. Any such updated Medical Device will be deemed to be the same product as the relevant Medical Device that it is updating such that the Price and all other terms that apply to that Medical Device will continue to 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 updated Medical Device in place of the original Medical Device pursuant to this Agreement until PHARMAC has given its approval for you to do so.

(c) If PHARMAC gives notice under (b) and 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 purchased the relevant Medical Device.

13.2 Upgrades in Medical Devices

(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 alternative to PHARMAC's right under (a), PHARMAC may choose to list any substitute medical device in Section H, Part III of the Pharmaceutical Schedule at the same price as the Medical Device being substituted/at a price mutually agreed between us and that medical device will become a Medical Device covered by this Agreement that is supplied by you on the same terms as the 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 and confirmed 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 and confirmed 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, which you confirm receipt of in writing;

(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 which you confirm in writing, either through the centralised purchasing system or separately if the centralised electronic purchasing system does not include a confirmation function; and

(iv) any other method approved by PHARMAC.

(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 purchased and the quantities; and

(iii) set out the Price of the Medical Device(s) being purchased, being the Price(s) as specified in Section H, Part III of the Pharmaceutical Schedule, both itemised for each Medical Device and with a total for all Medical Devices being purchased.

(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 (with a default limit of zero applying unless the DHB Hospital agrees a higher limit in writing). 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 24 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.

16. **Delivery**

(a) This clause 16 applies to all Medical Devices other than Consignment Medical Devices.

(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 purchased (including the product reference number as listed 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 confirmation of a Purchase Order where delivery is to a Logistics Provider;

(ii) three (3) business days of confirmation of a Purchase Order where delivery is to a DHB Hospital; or

(iii) such other period of time as may be specified in Part 8 in respect of a particular Medical Device.

For the purpose of this paragraph (c), a business day includes Saturday unless there are no courier delivery operators operating in the place of delivery that deliver on a Saturday morning and excluding any Saturday which is 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 am the business day following a Purchase Order being placed by a DHB Hospital or Logistics Provider where an urgent delivery request is made and confirmed by 3.00pm;

(ii) within 24 hours of a Purchase Order being placed by a DHB Hospital or Logistics Provider where an urgent delivery request is made and confirmed after 3.00pm; or

(iii) within such other period of time as may be specified in Part 8 in respect of a particular Medical Device.

For the purpose of this paragraph (d), a business day includes Saturday unless there are no courier delivery operators operating in the place of delivery that deliver on a Saturday morning and excluding any Saturday which is a statutory public holiday in New Zealand.

(e) Notwithstanding clause 22.1(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 any cap specified in Part 8 in respect of a particular Medical Device. In accordance with clause 22.1(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 confirmation 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 confirmation of a Purchase Order 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 confirmed and 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 confirmed 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 confirmed and 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 DHB 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 (i), 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 confirmed of 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. Any intention to change the packaging of the Medical Devices must 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 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 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 (the agreed supplier unit of measure) 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) manufacturer's name and/or Sponsor's name (as per WAND);

(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. Defective or undelivered Medical Devices and recalls

18.1 Defective/undelivered 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 Sale of Goods Act 1908, 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.

(c) On rejection of any Medical Device or if you default in delivering any Medical Device as required by the DHB Hospital or Logistics Provider (as applicable) or if any Medical Device is recalled as contemplated by clause 18.2, then, 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 Devices on giving notice to you and may purchase alternative product elsewhere. Any additional costs incurred by PHARMAC, the DHB Hospital, Logistics Provider (as applicable) in purchasing such alternative product, including any difference between the contract price and the actual cost of purchase of 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).

18.2 Recalls and safety concerns

(a) In the event that you recall or are required by government or any other authorities to recall or modify any or all of the Medical Devices you are required to inform PHARMAC and every DHB Hospital's contact or Logistics Provider's contact (as applicable), regardless of whether the DHB Hospital or Logistics Provider has purchased the relevant Medical Device, immediately by facsimile or email, communicating the full scope of the recall in order that PHARMAC and the DHB Hospitals can make the best clinical judgement regarding future use. You must also notify Medsafe in the event that the Ministry of Health has not required the recall itself.

(b) In addition to your obligation in (a) you must notify PHARMAC if you suspect that you may recall a Medical Device, or if a Medical Device may be required to be modified or recalled by government or other authorities, as soon as you are aware of such risk or possibility.

(c) You must also 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.

(d) You will similarly notify PHARMAC, the DHB Hospitals, the Logistics Provider (if applicable) and Medsafe if you become aware of any manufacturer supplied or independently sourced reputable reports of non-compliance that genuinely affect or have the potential to affect the safety of the Medical Devices. Subject to (e), you will use your best endeavours to provide Alternative Medical Devices to the DHB Hospital or Logistics Provider (as applicable) as soon as possible provided that the DHB Hospital or Logistics Provider (as applicable) reserves its right to purchase alternative products elsewhere if the DHB Hospital or Logistics Provider has concerns about the safety of the Medical Devices or does not wish to use the Alternative Medical Devices.

(e) For the purpose of providing an Alternative Medical Device as contemplated under (d), you agree to work closely with PHARMAC and to follow the process stipulated by PHARMAC in order to source and provide an Alternative Medical Device, which at a minimum includes obtaining PHARMAC's consent to the supply of the Alternative Medical Device as a substitute for a Medical Device.

18.3 Consequences of defective/undelivered/recalls and safety concerns of Medical Devices

(a) In the event that any Medical Device is rejected under clause 18.1(b) or if any Medical Device is recalled as contemplated by clause 18.2(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 Devices (including any Medical Devices 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 Alternative Medical Devices 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).

(b) You will not at any time substitute any Medical Device with any other medical device without first receiving written acceptance of the Alternative Medical Device from PHARMAC.

(c) This clause 18 confers a benefit on (and is enforceable by) DHB Hospitals and Logistics Providers in accordance with the Contracts (Privity) Act 1982.

19. No obligation to purchase minimum quantity

(a) Nothing in this Agreement will prevent any DHB Hospital or Logistics Provider purchasing 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) Nothing in this Agreement 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 under a minimum quantity or value unless Part 8 specifies that a minimum order quantity or value or an order fee or premium for ordering under a minimum quantity or value applies to the Medical Device(s) or to any Purchase Order placed and confirmed under this Agreement.

(c) If a minimum order quantity of a Medical Device or Medical Devices is provided for in Part 8, you may only charge the DHB Hospital or Logistics Provider a minimum order charge if this is expressly set out in Part 8 in respect of the particular Medical Device or Medical Devices. If no relevant minimum order charge is set out in Part 8, the minimum order charge shall be the Price of the Medical Devices ordered without any additional charges being applied to that order.

20. 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 that have been inadvertently and incorrectly ordered from you by the DHB Hospital or Logistics Provider through a Purchase Order (including where a DHB Hospital incorrectly orders Medical Devices from a Logistics Provider, which are in turn ordered from you through a Purchase Order), 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.

(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 any cap specified in Part 8 in respect of any Medical Devices.

(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 incorrectly ordered Medical Devices.

(g) For the avoidance of doubt, nothing in this clause requires a DHB Hospital or Logistics Provider to pay any administration and delivery costs to you for returning Medical Devices to you if you have delivered Medical Devices other than in accordance with a relevant and valid Purchase Order.

21. DHB Hospital or Logistics Provider sites

(a) 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.

(b) 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.

(c) 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 this clause and the DHB Hospital or Logistics Provider may deny access to any of your Personnel who do not comply with the requirements of this clause.

(d) 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.

(e) 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.

PART 4: Price and Payment

22. Price

22.1 Supply price

(a) The Price at which each Medical Device is supplied by you must not exceed the Price set out 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 specified 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 specified 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.

(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 education services or any other additional services that relate to the Medical Devices are as specified in Part 8 of this Agreement and subject to any special payment terms that may be specified in Part 8.

(h) Notwithstanding the provisions contained in this Clause 22.1, you and PHARMAC may by mutual agreement adjust the Price of each Medical Device listed in Schedule 1 of this Agreement. Any new prices shall be agreed in writing and shall apply from the date agreed between the parties.

22.2 Warranty that not less than cost price

You warrant that the Price at which you are required to supply each Medical Device, or in the case of Capital with Consumable Items Medical Devices, the Price at which you are required to supply the Capital Medical Device together with its package of consumable items and related services, if any (the **"Price Package"**) under this Agreement is greater than the cost price of that Medical Device, or the cost price of the Price Package in the case of Capital with Consumable Items Medical Devices (including, without limitation, the costs of manufacturing that Medical Device and of supplying it to you for supply in New Zealand).

22.3 Price adjustment if delivery is to a Logistics Provider

(a) In the event that the place of delivery of a Medical Device will routinely be to a Logistics Provider, you acknowledge that there will be a cost saving to you associated with this and you agree to a commensurate reduction in the Price to take into account that delivery of some or all Medical Devices to a central warehouse or central warehouses occurs in larger quantities and to more central and fewer locations. You agree to negotiate with us in good faith to agree on the amount of the reduction in Price and, failing such agreement, that the issues will be referred to dispute resolution or an independent expert for determination.

(b) Following agreement on a reduced price of a Medical Device under (a), we will amend the Price of the Medical Device in Section H, Part III of the Pharmaceutical Schedule to reflect the agreed change in the Price of that Medical Device.

22.4 Price adjustment for service or product optimisation

(a) If you find ways to optimise the Medical Devices of associated services that you supply or provide under this Agreement (including through employing new technology) such that the price at which you supply a Medical Device or any associated services could be reduced, you may submit a proposal to PHARMAC for PHARMAC's consideration and, subject to agreement between the parties, a variation to this Agreement may be entered into to reflect any such agreement reached between the parties.

(b) You may not submit a proposal referred to under (a) directly to any DHB Hospital or Logistics Provider.

(c) Subject to any agreement to the contrary in Part 8, PHARMAC may at any time adjust the Price at which any Medical Device is listed in Section H, Part III of the Pharmaceutical Schedule through utilising any of the mechanisms available to PHARMAC under the OPPs.

22.5 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 in Section H, Part III of the Pharmaceutical Schedule provided 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 in Section H, Part III of the Pharmaceutical Schedule; and

(c) in the event that the reduction in the price is to be a permanent reduction, notify PHARMAC that this is the case so that PHARMAC may, 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.

23. Invoicing

23.1 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 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.

23.2 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.

24. 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 23 above or any special invoicing arrangements in Part 8, 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 24 confers a benefit on (and is enforceable by) DHB Hospitals and Logistics Providers (as applicable) in accordance with the Contracts (Privity) Act 1982.

PART 5: Reporting and audit

25. Reporting

25.1 Reporting obligations

(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 Schedule 3.

(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.

25.2 Access to price and volume data

(a) You acknowledge that PHARMAC and its agents will require access to price and volume data held by you and DHB Hospitals in respect of each Medical Device covered by this Agreement to assist PHARMAC to carry out its statutory function in relation to managing the purchasing of medical devices on behalf of DHB Hospitals.

(b) Notwithstanding any other provisions in this Agreement, including clause 35 regarding confidential information, you agree that where the circumstances in this clause apply, a DHB Hospital may provide PHARMAC and its agents with any price and volume data held by that DHB Hospital in respect of a Medical Device covered by this Agreement and PHARMAC and its agents may provide such data to DHB Hospitals.

(c) You agree that within ten (10) business days following any request from PHARMAC, you will provide PHARMAC with volume data, in respect of each Medical Device covered by this Agreement for each month of the period specified in that request.

26. Audit

(a) PHARMAC may, from time to time, review your records and any other information you hold that relates 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 agree to remedy any non-compliance within ten (10) business days of receiving such notice from PHARMAC.

(c) PHARMAC may terminate the Agreement if you fail to remedy any area of non-compliance in accordance with (b).

PART 6: Consequences of failure to supply

27. Indemnities

27.1 Indemnity for failure to supply

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), and (only in the case of any non-supply of a Medical Device) if PHARMAC considers that such failure will result in the requirements of any patient of a DHB Hospital in relation to the Medical Device not being met. This indemnity covers all additional costs (including costs relating to purchasing or funding a medical device of a similar therapeutic effect to that Medical Device, and all actual legal expenses) incurred by the DHB Hospital and, if applicable, the Logistics Provider (or by PHARMAC on its behalf) as a result of your failure to supply the Medical Device in accordance with this Agreement.

27.2 Indemnity for general breach of the Agreement or negligent provision

(a) You indemnify each DHB Hospital and, if applicable, each Logistics Provider, and PHARMAC against any claims or costs (including legal and expert costs and expenses incurred on a solicitor/client basis) which may be made against the DHB Hospital, Logistics Provider or PHARMAC or which arise as a result of the breach of this Agreement or 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 losses, claims and expenses, including legal fees, incurred by the DHB Hospital or PHARMAC as a result of a breach of any patent, registered design, copyright or other protected right arising from the supply of the Medical Devices.

27.3 Indemnity in a recall situation

You indemnify each DHB Hospital, and if applicable each Logistics Provider, for any additional administration, surgery, patient appointment, patient care and other similar costs incurred by a DHB Hospital, and, if applicable, each Logistics Provider, in relation to rectifying a recall situation. This indemnity covers all costs incurred by a DHB Hospital or Logistics Provider in relation to removing and replacing a recalled Medical Device, notifying affected patients, clinicians and other medical professionals, and returning or otherwise dealing with recalled Medical Devices, as required.

28. Liquidated damages

(a) If you fail to supply a Medical Device in accordance with this Agreement (other than for reasons that PHARMAC considers to be a Force Majeure Event), whether as a result of your inability to meet demand for supply of that Medical Device, your withdrawal of that Medical Device from supply, any failure to have and maintain a Permit as specified in clause 9.3 above, or a Medical Device being recalled in accordance with clause 18.2, or for any other reason, and:

(i) you have not notified PHARMAC and the relevant DHB Hospitals and, if applicable, Logistics Providers, under clause 9.9, then in addition to your obligations under clause 9.9(b)(i) and (ii) 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 in respect of which you failed to notify PHARMAC; or

(ii) you have notified PHARMAC and the relevant DHB Hospitals under clause 9.9, then in addition to your obligations under clause 9.9(b)(i) and (ii), 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 $5,000 per Medical Device in respect of which you notified PHARMAC.

(b) You acknowledge and agree that:

(i) subject to (c) below, the amounts of liquidated damages in this clause represent 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 amounts referred to as liquidated damages are not intended to include any penalty element nor any amount for costs relating to the securing of an Alternative Medical Device, or the purchasing 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 relevant amount so specified.

(c) Where you notify PHARMAC under clause 9.9 above of a Potential Out-of-Stock Event, PHARMAC agrees to recover as liquidated damages under clause 28(a)(ii) only the amounts specified in clause 28(a)(ii), which represent only a portion of PHARMAC's and DHB Hospitals' costs actually incurred.

(d) All amounts referred to in this clause are plus GST (if any).

29. Default interest and recovery costs

If payment of any amount required to be paid by you under clauses 27 and 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 30 below, to recover that amount and you agree to pay PHARMAC actual enforcement costs incurred in relation to that action.

PART 7: General terms

30. 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 LEADR New Zealand Incorporated (Lawyers Engaged in Alternative Dispute Resolution), and the Chair of LEADR (or the Chair's 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.

31. 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.

32. 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.

33. 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.

34. Insurance

(a) You shall arrange and maintain (including for a 12 month period after this Agreement ends, should it do so for any reason, or for any alternative or longer period that is specified in Part 8 in respect of a particular Medical Device) adequate insurance policies for professional indemnity, products liability and public liability and, if Part 8 specifies a minimum level of insurance, up to at least the minimum level specified for the particular type of insurance in Part 8. You must notify PHARMAC of the level of each type of insurance held by you as soon as practicable after entering into this Agreement. If requested you will send a copy of the relevant policy renewals to PHARMAC and each DHB Hospital. Whether or not insurance policies exist shall not derogate from your potential liability under this Agreement.

(b) You will do nothing to invalidate the insurance policies that you hold as required under (a) or to prejudice your entitlement under those insurance policies.

(c) For the avoidance of doubt, this clause 34 survives for a period of 12 months after this Agreement ends, should it do so for any reason.

35. 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.

36. 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.

37. Notices

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

38. 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.

39. Time of the essence

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

40. 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.

41. 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.

42. 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.

43. 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.

44. 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 purchased 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.

45. 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 and Medicines Regulations 1984; or

(ii) industry standard, including the Advertising Standards Authority Codes of Practice and the Medicines 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.

46. Contracts privity

(a) For the purposes of the Contracts (Privity) Act 1982, 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.

47. 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.

48. Amendments

Amendments to this Agreement are only effective where the parties:

(a) have agreed to adjust the Price of each Medical Device listed in Schedule 1 in accordance with Clause 22.1 (h);

(b) have agreed in writing any other amendment to Schedule 1; or

(c) have agreed and signed a written amendment in any other event.

49. 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). 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.

50. 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.

51. 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.

52. 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.

53. 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 PTAC or its sub-committees, or any medical device advisory committee established by PHARMAC consider to be 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;

"Capital Medical Device" means a Medical Device listed in clause 2 of Schedule 1;

"Capital with Consumable Items Medical Device" means a Medical Device listed in clause 3 of Schedule 1;

"Category of Medical Device" means a Consumable or Durable Medical Device, a Capital Medical Device or a Capital with Consumable Items Medical Device, as applicable;

"Consignment Medical Devices" means a Medical Device to be placed on consignment (where use of the item by the DHB Hospital rather than delivery by you triggers when ownership of and risk associated with that Medical Device passes to the DHB Hospital) in a DHB Hospital's premises in accordance with clause 15;

"Consumable or Durable Medical Device" means a Medical Device listed in clause 1 of Schedule 1;

"Crown Direction" means any Ministerial direction given to PHARMAC under section 103 of the Crown Entities Act 2004;

"DHB Hospital" means a DHB, including its hospital or associated provider unit for which that District Health Board purchases medical devices;

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

"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 all intellectual property rights and interests, including copyright, trademarks, designs, patents and other proprietary rights, recognised or protected by law;

"Logistics Provider" means an entity contracted by a DHB Hospital to arrange purchase of and/or take delivery of a Medical Device required by the DHB Hospital;

"Material 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;

"Medical Device" means any medical device listed in Schedule 1;

"Medicines Act" means the Medicines Act 1981;

"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;

"Potential Out-of-Stock Event" means:

(a) your stock of a Medical Device falls below the average volume of stock of that Medical Device required to supply the entire New Zealand DHB Hospital market for that Medical Device for any given two month period;

(b) your stock of a Medical Device falls below two-thirds of your most recent three months' total unit sales of that Medical Device; or

(c) your forecast of sales demand in respect of the next two-month period is greater than your stock of a Medical Device;

"Price" means the price (exclusive of GST) at which a Medical Device is to be sold and supplied, or made available for sale and supply, 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 Annexure 1 to Schedule 1;

"Purchase Order" means an order for the purchase of Medical Device(s) as described in clause 14;

"PTAC" means the Pharmacology and Therapeutics Advisory Committee;

"Sponsor" means the sponsor of a Medical Device for the purpose of the Medicines (Database of Medical Devices) Regulations 2003, as notified to Medsafe in accordance with those Regulations.

54. 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.