Information for Company Representatives

PURPOSE

The purpose of this document is to advise suppliers of medical devices (products, equipment or services) and pharmaceuticals of the expectations Waikato District Health Board (Waikato DHB) have in relation to supplier conduct and introduction of a medical device and pharmaceuticals within Waikato DHB.

Implementation of these requirements will:

- mitigate potential risks to patients and staff related to the introduction of new medical devices and services
- ensure the necessary legislation and regulatory compliance is verified prior to the acceptance and introduction of a medical device
- minimise disruption to patient care through managing (pre-authorised) access to clinical staff (this definition includes clinicians, nursing, medical, scientific laboratory, radiology and allied health)
- comply with Waikato DHB's health and safety requirements
- comply with Waikato DHB's procurement and contracts policy

Acronyms

CPA	Clinical Product Advisor
CPC	Clinical Product Coordinator
DHB	District Health Board

CLINICAL PRODUCT RESPONSIBILITIES

The Clinical Product Coordinator (CPC) and Clinical Product Advisor (CPA) responsibilities are to ensure:

- relevant Waikato DHB clinical and technical specialist staff are involved in reviewing the product
- compliance, legislation and regulatory responsibilities are reviewed, found complete and compliance verified
- review and follow up of all medical device related risks and incidents
- education is arranged where required and records of supplier provided education maintained

CPCs meet with supplier representatives on alternate Monday mornings or by prior appointment.

The Procurement Team:

- The term 'procurement' covers all aspects of acquiring and delivering products, services and works.
- It starts with identifying the need and finishes with either the end of a product or service contract or the end of the useful life and disposal of the asset.
- The procurement lifecycle covers market research, approaching the market, evaluating responses, negotiating and awarding contracts and managing the contracts.

VISITING A CLINICAL AREA TO DISCUSS AN EXISTING OR NEW PRODUCT

Company representatives are able to call on a ward or department when:

- They have an existing product used in the clinical area and have a confirmed appointment time to see a clinical staff member and the visit is related to technical advice, support or education of an existing products; or
- They have been requested by clinical staff to visit for a specific purpose, and have a confirmed appointment.

Company representatives are requested to comply with the industry Medical Trade Association NZ Code of Practice. Under the Government Procurement Rules suppliers must adhere to the Supplier Code of Conduct.

Information for Company Representatives

When onsite at a Waikato DHB facility the company representative is 'sponsored' by an authorised staff member. In most instances the 'sponsor' will be the facilitator of the meeting to which the representative has been invited to attend or a person delegated to take on this role. The 'sponsor' is responsible for the visitor while they are visiting Waikato DHB and will inform them of any Waikato DHB policies that relate to the purpose of their visit.

It is the responsibility of the company representative to comply with these policies e.g. fire evacuation, patient privacy, infection prevention and control, clothing & hygiene standards. Departments within the DHB may have area specific requirements which the sponsor is required to inform the representative of as soon as possible.

Company representative must wear their own company identification, and are not to conduct meetings or education in cafeterias, staff refreshment areas or corridors. It is the responsibility of the sponsor of the visit to ensure a suitable area is available for meeting or education purposes.

Process:

1. Contact the clinical area to make an appointment. Advise the clinical area of date/s of visit, purpose of visit, and person/s requesting to see.
2. Contact CPC if unsure who to approach in a clinical area for guidance.
3. Follow the guidance/criteria/rules set by the area if they can accommodate your request.
4. The clinical area will make contact with CPC if interested in the new product you are promoting.

Note:

- Under no circumstance should the company representative make unsolicited visits.
- Company representatives should not leave samples unless approved by CPC.

COVID19 and INFLUENZA

All staff entering DHB premises must comply with the COVID-19 Public Health response (Vaccinations) Order 2021. DHB policies may impose other requirements or restrictions during certain times; sponsor and/or CPC will advise you accordingly.

CLINICAL PRODUCT EVALUATIONS

Clinical product evaluations are coordinated by the CPC team. This may or may not be part of an active tender process. During a tender process no contact should be made by supplier representatives while products are undergoing clinical evaluation unless arranged through the CPC team.

Dependant on the structure of the clinical product evaluation, a form may be developed by CPC team for DHB use. This form is not to be collected or viewed by involved supplier staff while the evaluation is in process. Failure to comply may result in the termination of the evaluation or voiding of suppliers results. The completed evaluation form remains the property of Waikato DHB. A summation of the results is available on request, on completion of project.

While the clinical product evaluation is underway staff from competing companies, either directly or indirectly involved in the evaluation, will have limited/controlled access during this time.

TENDERS

The Procurement Team is responsible for the central management and oversight of all Waikato DHB procurement processes and systems. All procurement activity at Waikato DHB is directed by the Procurement and Contracts Policy.

Waikato DHB is a core Crown agency who are mandated to follow the Government Procurement Rules.

A key focus of the Rules is the importance of open competition – giving all businesses the chance to participate, and giving them enough time to respond to opportunities properly. They also help to:

- align New Zealand procurement practice with international best practice
- encourage more strategic procurement approaches
- foster competition and innovation, resulting in better solutions
- promote broader environmental, social, cultural and economic outcomes.

The Five Principles of Government Procurement:

1. Plan and manage for great results
2. Be fair to all suppliers
3. Get the right supplier
4. Get the best deal for everyone
5. Play by the rules

At all times during at any stage during the tender process (unless enquiry is specific to the clinical product evaluation, see above) a company representative should contact Procurement.

CONSIGNMENT AND PRODUCT STOCKTAKES

Company Representatives entering the DHB to conduct stocktakes on consignment stock are to make contact with the Consignment team before entering service area. A Consignment team member must be present with the Representative during the stocktake. Documentation of stock management is the responsibility of both the company representative and Consignment team member.

RECALLS, NOTIFICATIONS, FAULTS AND EDUCATION

Contact the CPA 48 hours before (whenever practicably possible) a visit which relate to recalls, faults or education. Advice date/s of visit, purpose of visit, and person/s requesting to see.

Education & in-servicing: Visits require email notification to the service and CPA with a synopsis of the in-service. A copy of attendee list must to be forwarded to the CPA post in-service.

Recalls & notifications: Company representatives may enter Waikato DHB premises in the event of a medical device recall or notification if required after discussion with the CPA (or delegate). Communication on the incident should be with the CPA (Medsafe recall contact) unless otherwise agreed.

Device/product fails: Company representatives need to liaise with the CPA in the event a product/device fails before removing the device/product from the DHB for remedial action.

OUT OF STOCK/ALTERNATES

Product which is short supply or out of stock is to be communicated to Inventory Implementation as soon as possible to enable a planned approach to sourcing an alternative and management of current stock.

Any alternative must comply with requirements of PEHNZ and WAND. A sample may be required for review.

CONTACT DETAILS

CPC	cpc@waikatodhb.health.nz
CPA	clinicalproductquality@waikatodhb.health.nz
Purchasing Helpdesk	PurchasingHelpdesk@waikatodhb.health.nz
Procurement	Procurement@waikatodhb.health.nz
InventoryImplementation	InventoryImplementation@waikatodhb.health.nz
Consignment Services	ConsignmentServices@waikatodhb.health.nz
Pharmacy Services	PharmacyProcurement@waikatodhb.health.nz

LINKS

MTANZ Code of Practice 6th Edition 2016

http://www.mtanz.org.nz

MTANZ copy of PEHNZ form

https://mtanz.org.nz/filescust/CMS/PEHNZ Form 2020 FInal.docx

Waikato DHB Visitors Policy

https://www.waikatodhb.health.nz/patients-and-visitors/business-visitors/

https://www.waikatodhb.health.nz/your-health/covid-19-in-waikato/covid-19-visitors-policy/

New Zealand Government Procurement Supplier Code of Conduct

https://www.procurement.govt.nz/broader-outcomes/supplier-code-of-conduct/