INFORMATION FOR COMPANY REPRESENTATIVES

PURPOSE

The purpose of this information pamphlet is to provide suppliers' company representative/s 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 within Waikato DHB.

Implementation of these requirements will:

1) mitigate potential risks to patients and staff related to the introduction of new medical devices and services
2) ensure the necessary legislation and regulatory compliance is verified prior to the introduction of a medical device
3) 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)
4) comply with Waikato DHB's health and safety requirements
5) comply with Waikato DHB's procurement and contracts policy

NEW PRODUCTS

Company representatives wishing to promote medical devices (products, equipment or services) which are not currently used within Waikato DHB (i.e. new products), or is a variation to an existing item, must make an appointment with the Clinical Product Coordinators to facilitate discussion on the product. Pharmaceutical suppliers must contact Waikato DHB Pharmacy.

MAKE AN APPOINTMENT

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

1. 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
2. They have been requested by clinical staff to visit for a specific purpose.

Company representatives are not to make unsolicited visits.

- Any unsolicited visit includes, but is not limited to, a company representative showing a clinician new product without their prior knowledge (as it happens to be in the representative's possession)

KEEPING INFORMED

Company representatives must advise the following of their visit:

1. Clinical Product Coordinators 48 hours before (wherever practicably possible) all visits including Rural Hospitals; Community Services (District Nursing, Dental etc)
   cpc@waikatodhb.health.nz
2. Clinical Product Advisor 48 hours before (whenever practicably possible) of any visits which relate to recalls, faults or education. Following all education sessions delivered to DHB staff, a copy of the attendee list is forwarded to Clinical Product Advisor by the supplier representative
   Helen.Cameron@waikatodhb.health.nz
3. Service or Clinical Leaders and / or Charge Nurse Manager or equivalent on arrival for a visit;

Included within the email notification the following information is required:

- Date(s) of visit
- Purpose of visit
- Person visiting
- What products supporting/promoting
- Synopsis of intended education where appropriate

4. During the influenza season it may be necessary for you to advise your vaccination status to the Clinical Product Coordinators. If you are not vaccinated for the current year's influenza virus(es) or cannot provide evidence of your vaccination you will be required to wear a protective mask whilst you are in clinical areas or meeting with staff from clinical

areas. Waikato DHB will provide an appropriate mask for any visitor that has not been vaccinated or cannot provide evidence of vaccination.

CONTRACTS

Any purchases and/or contracts relating to service or supply of new medical devices must involve the Clinical Product Coordinators and Procurement from the outset.

TENDERS

Company representatives are not to contact or visit clinical staff where products are being evaluated during the tender process. All communication is to be through the Procurement Department.

SIGN-IN PROCEDURE

All company representatives are required to sign in and out when visiting Waikato DHB facilities. They must wear the assigned visitor identification and their own company identification during the visit.
Sign in books are located at:

For visiting Theatre or Gastro/Endoscopy Departments –	
Day of Surgery Admission Unit (DOSA), Reception K, in the Meade Clinical Centre, Level 3	Monday to Friday 0700- 1630
Notes/check points relevant to entering DHB via DOSA • Have notified CPC via cpc@waikatodhb.health.nz 48hrs prior (where possible) of who, when, why and department/location. • If your name is not on the Visiting Company Representatives List. You will be directed to contact the CPCs. Access will not be given until CPC have given approval. • The DOSA receptionist will check you have notified the appropriate personnel before directing you to the change area. • On the conclusion of your visit , return to Reception K and sign out of the visitor book and return your access card. • Leaving the department after 5pm deposit your access card in the box on the side of the scrubs cupboard. • If you fail to return your access card, you will be contacted by phone the next working day. Failure to return within 24 hours will incur a replacement charge of $125 and will not be issued another until paid. Cards are issued on first come first served basis.	
For all other areas at Waikato campus –	
Enquiries Desk Acute Services Building outside ED	Monday to Friday 0800 - 2000 Weekend and Public Holiday 0830 - 1700
Notes/check points relevant to entering DHB via ED • Have notified CPC via cpc@waikatodhb.health.nz 48hrs prior (where possible) of who, when, why and department/location. • Failure to sign out and return the 'Visitor' card will be documented. If this occurs three times future admittance to the DHB may be denied	

All other Waikato DHB locations	As per local arrangement (a visitor sign in / sign out book is usually located at the front desk)	As per local arrangement

ON-SITE

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, visiting a restricted area such as operating theatre and wearing a mask as necessary during the influenza

	season. 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 are 'privileged visitors' and must wear the approved Waikato DHB identification and their own company identification. Failure to do so may mean those company representatives are asked to leave the area and only return with the appropriate identification. Company representatives 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.
PEHNZ and WAND INFORMATION	All new medical devices must have the appropriate Certification, WAND notification and PEHNZ forms completed. WAND notification of medical devices is a Ministry of Health directive and is a mandatory requirement prior to use within the Waikato DHB. These documents are to be forwarded to the Clinical Product Coordinators on request.
PRODUCT RECALL	Company representatives may enter Waikato DHB premises in the event of a product recall only if deemed required after consultation with the Clinical Product Advisor (or Coordinator if unavailable). All communication should be made directly with Clinical Product Advisor unless otherwise agreed
DEVICE FAILURES	Company representatives who are either present on Waikato DHB premises when a device/product fails in use, or are contacted directly by the users when/after a device/product has been identified as failed, are to ensure the Clinical Product Advisor is informed immediately in order to facilitate the DHB reporting process requirements are adhered to, and assure safety of the device in question where necessary, before it is provided to the company for manufacturer QA processing. It is not acceptable for the company representative to remove the device/product from Waikato DHB premises without first contacting the CPA role to gain approval.
EDUCATION	Visits for the purpose of product education & in-servicing, require notification as per standard process with the inclusion of the CPA in the email and a synopsis of the in-service. An attendee list needs to be forwarded to the CPA post in-service Where companies wish to offer sponsored or facilitated education opportunities to Waikato DHB staff, it is necessary for this to be advised well in advance to CPC and CPA roles. This includes any financial assisted or incentivised aspects of the opportunity being offered – meal provision, travel supported, registration etc. Approval must be given before the company proposes the offer to intended DHB staff.
SAMPLE SUPPLY	No samples are to be supplied to clinical staff unless approved by a Clinical Product Coordinators. After a formal request is made samples will be sourced as part of the evaluation process.
CONSIGNMENT AND PRODUCT STOCKTAKES	All Company Representatives entering the DHB to conduct stocktakes on consignment stock are to make contact with the Consignment team before entering 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. Normal notification of visit and sign in is expected to be completed.
QUOTES	Any quotes given or emailed to DHB staff are to be copied and sent to CPC to ensure products are not being supplied without proper approval

CODE OF PRACTICE	Company representatives must comply with the industry Medical Trade Association NZ Code of Practice.
NEW COMPANY REPRESENTATIVES	Suppliers should ensure the Waikato DHB Procurement Department is informed of personnel changes. Suppliers also need to inform their new employees of Waikato DHB requirements for visiting company representatives. New supplier staff will meet with Clinical Product Co-ordinators for induction to Waikato DHB processes, as soon as possible after commencing tenure.
CLINICAL PRODUCT RESPONSIBILITIES	The Clinical Product Coordinator (CPC) responsibilities are to ensure: • all Medical devices (new or replacement) that are offered to Waikato DHB for continued use is managed in a co-ordinated manner • all relevant Waikato DHB clinical and technical specialist staff are involved in reviewing the product • Procurement staff are involved and aware of medical devices being considered for use, where appropriate (price and conditions, negotiation, tender, contract. etc) • compliance, legislation and regulatory responsibilities are reviewed, found complete and compliance verified The Clinical Product Advisor (CPA) responsibilities are to ensure: • all medical device related risks reported are attended to promptly • implementation planning for medical devices to commence use is facilitated • education is arranged where required and records of supplier provided education maintained The Clinical Product Coordinators meet with supplier representatives on a Wednesday morning by prior appointment. Meeting time exceptions will only be made for progress to do with projects that are already underway, or where a clinical product related issue is cause for concern.
Contact details	• Steven Trotter – CPC *Steven.Trotter@waikatodhb.health.nz* • Janette Webster – CPC *Janette.Webster@waikatodhb.health.nz* • Generic email account for CPC *cpc@waikatodhb.health.nz* • Helen Cameron – CPA *Helen.Cameron@waikatodhb.health.nz*

Waikato District Health Board reserves the right to exclude suppliers/representatives from its premises who do not fully comply with these requirements. Failure to follow these requirements may result in total exclusion of the representative from all Waikato DHB premises for a period of up to three months

Owner

Clinical Product Coordinators – Waikato DHB
Clinical Product Advisor – Waikato DHB

References

MTANZ Code of Practice 6th Edition 2013
http://www.mtanz.org.nz

MTANZ copy of PEHNZ form
http://mtanz.org.nz/NZ-Market-The-NZ-Healthcare-Market/Procurement-6376.htm

Waikato DHB Visitors Policy
http://www.waikatodhb.health.nz/for-patients-and-visitors/business-visitors/