

DART NEWSLETTER

April 2010



Welcome to the Eighth DART Newsletter

The new WAND IT platform is working well. Medsafe has received feedback that sponsors are pleased with the increased functionality the development of New Zealand WAND has provided.

The purpose of this DART newsletter is to provide you with some extra helpful hints, to help you find your way around the new computer system, and manage the NZ WAND database efficiently.

Helpful Hints

WAND Access

The old Medsafe version of WAND was linked to the Australian DEAL (Devices Electronic Application Lodgement) notification system managed by the TGA. The TGA system permitted creation of a Master Sponsor ID account, and additional accounts for many different users e.g. Master 46792, and Johnny_46792, or Mary_46792.

The new version of WAND only requires the Sponsor ID (i.e. 46792) as the User ID, and one generic password. Medsafe generates the password and sends it to the New Zealand WAND Administrator for your company.

Please contact the New Zealand WAND Administrator for your company to obtain the password, for your WAND account.

Sponsor Details

As a Sponsor of a medical device you need to ensure that your contact details are current. If your details change you are required to notify Medsafe within 10 working days. Please remember that the person who is nominated as your New Zealand WAND Administrator is the one who will receive communications from Medsafe, such as a new password if the password needs to be re-issued. Failure to keep this information up-to-date may result in you not receiving important information.

Every time you log onto New Zealand WAND you will be asked if your details are up-to-date and current.

If your details are current you only need to click yes.

You do not need to send a “Sponsor Details Update Form” to Medsafe every time you log on to WAND. You only need to send the “Sponsor Details Update Form” if your details have changed.

If you accidentally press “No” just click “cancel”. This will not delete your contact details, it will just confirm that your details do not need to be updated.

Consultants

If you are a consultant, and you submit a New Zealand WAND Access Application (on behalf of a Sponsor), Medsafe requires a letter of authority to be completed by the Sponsor. It is preferable that a letter written on company letterhead is attached to an email notification.

New Zealand WAND allows for only one level of access. It is not possible to set up separate accounts for individual users.

All Individual **Sponsors** must develop a system to manage multiple users including consultants who may notify devices on their behalf. Medsafe does NOT do this for each Company.

In order to manage multiple users, Sponsors may wish to consider one of the following:

- In the “Sponsors Own Reference Field” each User could enter their own initials.
- The New Zealand WAND Administrator could create a Master Excel document on behalf of the company. All Users could access this document, and enter details of all their own notifications.
- All Users could maintain a history of their own WAND notifications.

Also, please note you can log onto New Zealand WAND (using your Sponsor ID), and refer to the navigational panel on the left hand side of the home screen by selecting “device search” you may search for your medical device notifications under five alternative fields. For further details please refer to page 30 of the “New Zealand WAND User Guide/Instructions for Use”.

Devices That Contain Medicines

Before notifying medical devices that contain a medicinal component (for example, bone cement with antibiotics) it is essential to ensure that specific risks associated with the medicinal component have been mitigated. Please contact Medsafe for advice.

Please send the email to Medsafe at DART@moh.govt.nz

Regulatory Statement to a Foreign Government

NZ Companies wishing to export medical devices may apply for a “Regulatory Statement to a Foreign Government”. This statement outlines New Zealand’s legislative requirements for medical devices. “A Regulatory Statement to a Foreign Government” is only issued to companies that manufacture their products in New Zealand.

Please send a formal cover letter/email of request to the DART mailbox. The request should include:

- The Sponsor’s name and address
- Name of the medical device
- Individual WAND numbers

A Medical Device Advisor will be happy to assist you, and guide you through the process. Medsafe cannot process your application unless **all** the correct information is supplied. Please note that this process may take at least up to 7 working days.

IVD’s (in vitro diagnostic devices)

Under New Zealand legislation it is not mandatory to enter an IVD notification to WAND. However, with the changes that were made to the system, we have included a special classification of “IVD” so that you now have the option to notify an IVD to WAND.

Please note that we receive a high volume of queries to the DART mailbox. We endeavour to respond to all queries as soon as possible although (rarely) this may take up to 20 working days.

If you need any help/revision, please refer to the previous DART newsletters, consult the WAND manual, or read the Frequently Asked Questions (FAQs). All documents are available on the Medsafe website www.medsafe.govt.nz. If you have any further questions please send an email to a Medical Device Advisor DART@moh.govt.nz.

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