

## DART NEWSLETTER

November 2009



### Welcome to the Seventh DART Newsletter

It is that time of year again! Summer and the festive season are coming up fast; and we wish you, your families and friends all the best for a happy, fulfilled and safe holiday.

We are very busy here at Medsafe implementing the new WAND IT platform and dealing with a huge amount of enquiries from our Sponsors. You should have received notification via email and seen the changes on the Medsafe website by now.

Thank you to those who have participated in testing the new WAND system and for all of the feedback that has been provided so far. We would also like to thank you all for your patience throughout this process.

### The New WAND IT Platform

The new WAND database has increased functionality of the WAND system quite significantly, providing Sponsors with options such as the ability to change or reset your WAND password, to edit submitted WAND notifications, keep or change notifications in draft format, to delete (obsolete) submitted notifications, and to notify ingredients and components of medical devices.

You can also make a request for a new manufacturer to be added to the Medsafe code table and update your contact details online. The ability to manage your own user access and maintain your own records will allow much greater control over your submitted information without delay.

1. Please, take time to carefully read the new WAND manual and FAQs before logging in and starting to use the new WAND database. Although the system looks very similar there are some fundamental changes that you must be aware of.
2. Please Note: A small number of notifications that were submitted during the interim WAND period may not have been transferred to the new system. This may be as a result of transcriptional errors during the transition.
3. Check your notifications on WAND. If a notification cannot be located a new notification will need to be created.

If you are still having issues you can send us a request in writing via email [dart@moh.govt.nz](mailto:dart@moh.govt.nz) for further assistance.

### Website Update and Change of Details

There have been a lot of changes to the Medical Devices Area of the Medsafe website which has prompted a few queries from Sponsors around WAND access.

New WAND no longer has different levels of access. Each Sponsor has only **ONE** User ID and password that the nominated New Zealand WAND Administrator for the company is responsible for. It is up to each Sponsor how you manage access to your account.

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 that is nominated as your New Zealand WAND Administrator is the one who will receive communications from Medsafe such as a new password if you lose it and it has to be reset. Failure to keep this information up-to-date will result in you not receiving important information.

Please, check if your contact details are correct each time when you log on WAND.

If you reset your password but do not receive a new one via email it may be that the message has gone to a SPAM folder or has been blocked as it is a system generated email. You may be able to resolve this issue by giving the following email address to your IT support so that it can be included as a trusted source. This should then allow the messages to come through.

The address is: [medsafe@webhostinginfinity.co.nz](mailto:medsafe@webhostinginfinity.co.nz)

Take care when entering your login details to WAND as you only have 3 attempts to get it right, the system will lock you out after three login errors. Initially when using the system generated password we recommend that you use the copy and paste functions to avoid typographical errors.

If you forget your password you can reset it by entering your Sponsor ID into the box below entitled "Forgot your password?", this action will automatically change your existing password so that a new one is sent to the New Zealand WAND Administrator.

If you are still having problems or require extra assistance you can contact us via email [dart@moh.govt.nz](mailto:dart@moh.govt.nz)

### **DEAL Copies**

As you are aware from the previous newsletter, you can no longer create a DEAL copy. Those notifications that are DEAL copies are still valid as long as the information in them is still correct. The DEAL clone that was created may have been from an ARTG entry that has since changed, Any changes to the original notification would not automatically be made on the DEAL copy in WAND, Therefore, if there are changes to the original entry you will need to update the WAND notification manually. If a notification ceases to be accurate Medsafe must be notified within 10 days and changes made accordingly (including any deletions)

### **Devices That Contain Medicines**

Before considering medical devices which contain a medicinal component, (for example, bone cement with antibiotics) it is essential that you ensure that the medicine has consent for supply in New Zealand. You can email all of the details to us at [dart@moh.govt.nz](mailto:dart@moh.govt.nz) and we will help you.

### **Helpful Hints**

When you make a request to add a new manufacturer to WAND, the following information must be provided: the current **street** address (not a post office box), direct phone number, email address and web page. This will allow us to process your request without delay.

When adding ingredients to a device notification, please ensure that you use the correct spelling (otherwise it may not be recognised by the system). You should only need the first 3 or 4 characters to get a list of products so that you can select the exact ingredient from the drop down box.

If the ingredient is not on the list, please send us a request for inclusion of the ingredient via our email address: [dart@moh.govt.nz](mailto:dart@moh.govt.nz) and we will add it following our review procedure.

### **Manufacturing Evidence**

With the implementation of the new WAND system we are no longer recommending that Sponsors submit manufacturer evidence however, we do recommend that you hold manufacturer evidence or ensure that you are able to access it if we request a copy from you.

### **Feedback**

Any feedback regarding this newsletter and issues related to medical devices is valued and can be directed to [dart@moh.govt.nz](mailto:dart@moh.govt.nz). Your opinions and suggestions help us to determine the most useful information to provide to our medical device Sponsors. All newsletters are available on the Medsafe Website at [www.medsafe.govt.nz](http://www.medsafe.govt.nz).

Ruth Grant  
Team Leader Medical Device Regulation  
Medsafe.