

DART NEWSLETTER

December 2008



Welcome to the sixth DART Newsletter

It is that time of year again! The festive season is upon us, we wish you, your families and friends all of the best for an exciting, fulfilled and safe holiday.

We are very busy here at Medsafe implementing the changes to the WAND database as quickly as possible. You should have received our mailout, an email and seen the changes on the website by now. If you haven't received this information from us you need to contact your DART adviser or send an email to dart@moh.govt.nz stating your sponsor name, New Zealand address, phone number etc so that we can ensure that we have the most current contact details for you on file.

Thank you to those who have given us feedback during this process and thank you all for your patience.

Read-only version of the WAND database

The new WAND database should be up and running early next year, currently we are between the old WAND and the new WAND in what we call the "interim" period. This means that the existing WAND database is 'Read-only' therefore you can only view and print out any entries that were on WAND prior to October 29.

Using the new process, when you submit a notification using the new webform, a screen opens that displays the WAND number that has been allocated to your device. It is recommended that you print this screen for your own records. You will not be able to view these notifications until we have new WAND in operation.

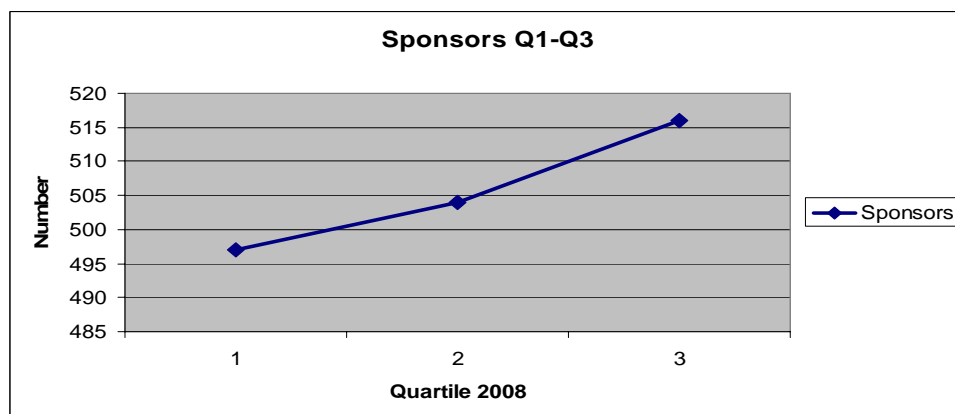
If you need any information regarding notifications submitted during this interim period, please send a request in writing via email to your DART adviser or email DART@moh.govt.nz

Update re Statistics of device Notifications on WAND

The statistical analysis below shows the trends and patterns of medical devices notified on WAND during the first three quarters of 2008.

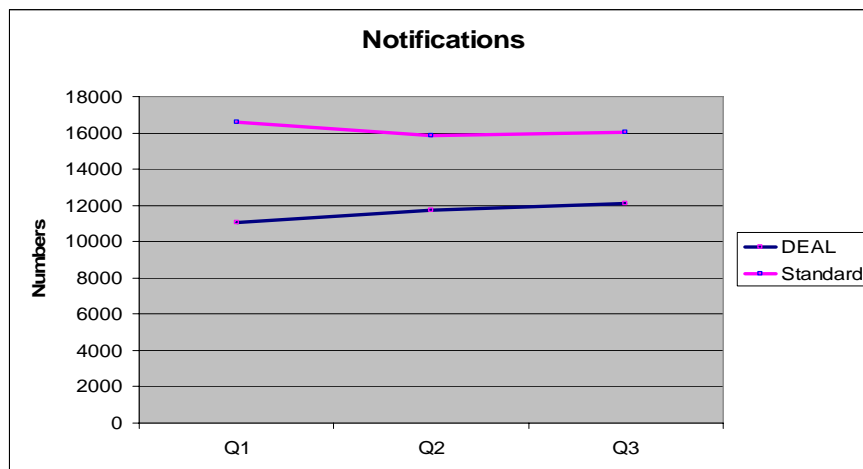
- Currently there are 28124 device notifications on WAND, up by 514 from the first quarter
- Currently there are 12090 DEAL copies on WAND, an increase of 1062 notifications
- The largest increase was for class I's – up by 245 notifications
- There have been 29 new sponsors added to WAND, taking the current total to 516

Line graph depicting the increase in number of new sponsors on WAND from Q1 to Q3 2008



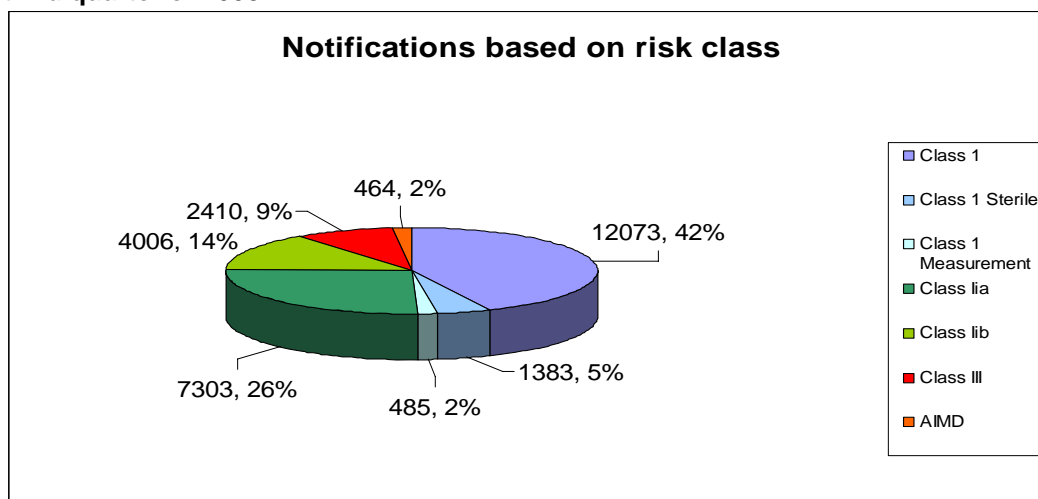
This shows that there is a steady increase in the number of new sponsors entering the NZ market.

Line graph depicting the trend of the number of notifications on WAND from Q1 to Q3 2008



This shows that there is a larger number of original notifications than DEAL copies on WAND.

Pie graph showing the number of device notifications based on their risk classification in the third quarter of 2008.



This chart shows that the lower risk Class I devices make up almost half of all entries on WAND.

Review of Class I Device entries in WAND

The review of basic Class I devices has been completed (excluding DEAL copies).

Some sponsors have already received feedback regarding their notifications on WAND, however all feedback will be processed and completed early 2009 to correspond to the system changes which will make the process much simpler.

Website Update and E-Business Queries

There have been changes to the Medical Devices Area of the Medsafe website which has prompted a few queries from sponsors around WAND access. Please take time to read the information that was sent out to you about the changes, if you cannot locate this information it can also be found on the website under **Important Changes on the WAND System Occurring 29 October 2008**** [read more](#).

To access and manage your user accounts for Read-Only WAND, you click on the link [Master Account Access and User Management for Read-Only WAND](#) and use your MASTER login e.g. master12345 and password.

To access Read-Only WAND in order to view notifications that were on WAND prior to October 29 click on [To view a notification \(submitted before 28 October 2008\) in Read-Only WAND](#) and enter your user ID e.g. user_12345 and password.

To enter a new notification click on [To submit a new WAND notification login](#) and enter your user ID e.g. user_12345, there is no password required for the interim process.

A full set of instructions can be found at [Instructions for the Interim WAND Notification Process \(29 October 2008-2009\)](#). Information related to the submission of Manufacturing Evidence is also available in these instructions on page 18, Step 7.

If you are still having problems or require some extra assistance you can contact your DART adviser to assist you. Alternatively, if you don't know who your adviser is you can email DART@moh.govt.nz

Changes to company name, address, agency etc

During the WAND update project we have come across a number of invalid addresses and obsolete contact details for sponsors, which means that emails and letters have been returned to us. We have tried to find forwarding addresses but it has been very time consuming and we do not always succeed. Each sponsor is responsible for maintaining the accuracy of the information that is on WAND, where the information has been mandated the legislation stipulates that "the sponsor must, within 10 working days of the information ceasing to be accurate or complete, ensure that the Director-General or any person who maintains the database on behalf of the Director-General is notified of the correct details, or the complete information, as the case requires."

Please let your DART Advisor know if there are any changes to your contact information. This is a requirement to comply with the current legislation.

Helpful hints

IVD's (in vitro diagnostic devices) are medical devices, but they are currently exempt from notification to WAND under New Zealand legislation.

DEAL copies are no longer accepted as notifications, even when the updated WAND is up and running early 2009.

Feedback

Any feedback regarding this newsletter and issues related to medical devices is valued and can be directed to DART@moh.govt.nz. Your opinions and suggestions help us to determine the most useful information to provide to our medical device sponsors.

Ruth Grant
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Devices
Medsafe