

## DART NEWSLETTER

June 2008



### Welcome to the 5<sup>th</sup> DART Newsletter

Brrrr..... We hope you are all buckling down for winter and staying warm!! We have passed the shortest day, so there is a light at the end of the tunnel!

We have been very busy here at Medsafe, within the Medical Devices team. Not only have we been gathering information on devices within New Zealand that may contain Heparin but we have been charging ahead with our Review of Class I notifications on the WAND database.

### Disappointing response to urgent request

The response to the urgent request for information regarding medical devices that may contain Heparin has been extremely disappointing, with only about 50% of our Sponsor's replying. This level of response to a request that may impact on public health is unacceptable. A response is required to show acknowledgement even if the issue does not affect you.

### Update on Class I Review in WAND

We are making tremendous progress with our review of Class I medical devices in the WAND database here at Medsafe. To date, we have completed 6747 initial Class I Reviews. We expect to start sending out feedback letters in the next few weeks

It is a big task and will take some months to complete as each Class I WAND notification is reviewed individually by a DART Team member. Upon completion of each company's Class I notifications, your assigned DART Advisor will send an initial feedback letter concerning the quality of data on WAND for your company. To assist us with this task we ask that you keep your notifications on WAND current and notify your DART Advisor of any devices that you are no longer supplying.

**DART Email:** [DART@moh.govt.nz](mailto:DART@moh.govt.nz)

Just a reminder that if your company has medical devices notified to the WAND database, your company will also have been assigned a DART Team Advisor. Please maintain contact and direct all of your company's enquiries to that specific Advisor. For E-business issues (ie- Master ID and Password problems), or any NEW company enquiries, please send your e-mail to [DART@moh.govt.nz](mailto:DART@moh.govt.nz).

### Issues Concerning Australian Companies

All Australian based companies wishing to distribute medical devices within New Zealand, must have a physical New Zealand address and a physical New Zealand Sponsor (as defined below). The following definition has been extracted from the **Medicines Act 1981** and the **Medicines (Database of Medical Devices) Regulations 2003**. You can view a full copy of the legislation at [www.legislation.govt.nz](http://www.legislation.govt.nz)

**Sponsor"**, in relation to a medical device,—

a. means—

- I. person in New Zealand who exports, or arranges the exportation of, the device from New Zealand:
- II. person in New Zealand who imports, or arranges the importation of, the device into New Zealand:
- III. a person in New Zealand who manufactures the device in New Zealand, or arranges for another person to manufacture the device in New Zealand, for supply (whether in New Zealand or elsewhere); but

b. does not include a person who—

- I. exports, imports, or manufactures a device; or
- II. arranges for the exportation, importation, or manufacture of a device,—

on behalf of another person who, at the time of the exportation, importation, manufacture, or making of the arrangements, is a resident of, or is carrying on business in, New Zealand

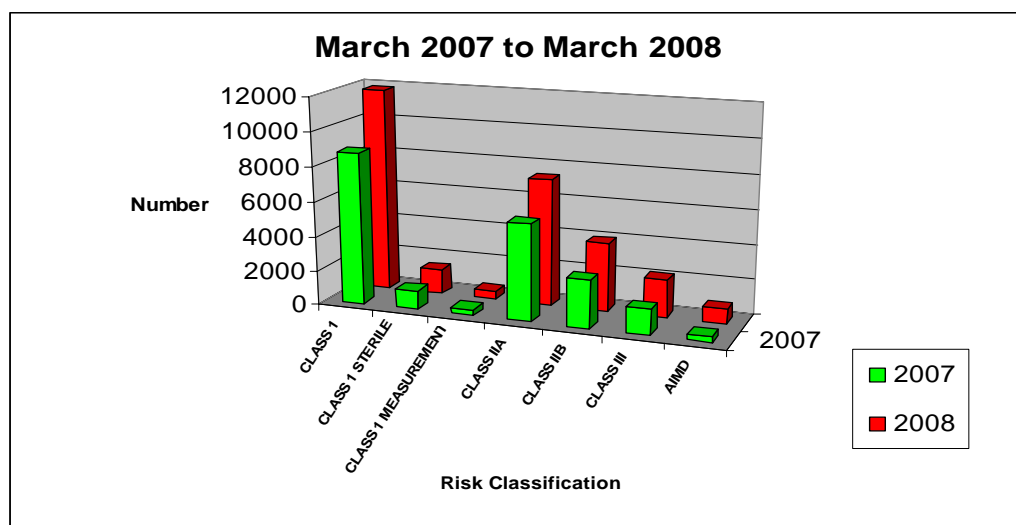
### Update re Statistics of device Notifications on WAND

The statistical study of trends and patterns of medical devices notified to WAND continues and has proven to be a very effective tool in analysing the emerging data.

The analysis undertaken to March 2008, show a significant increase in notifications in comparison to the snapshot taken in March 2007

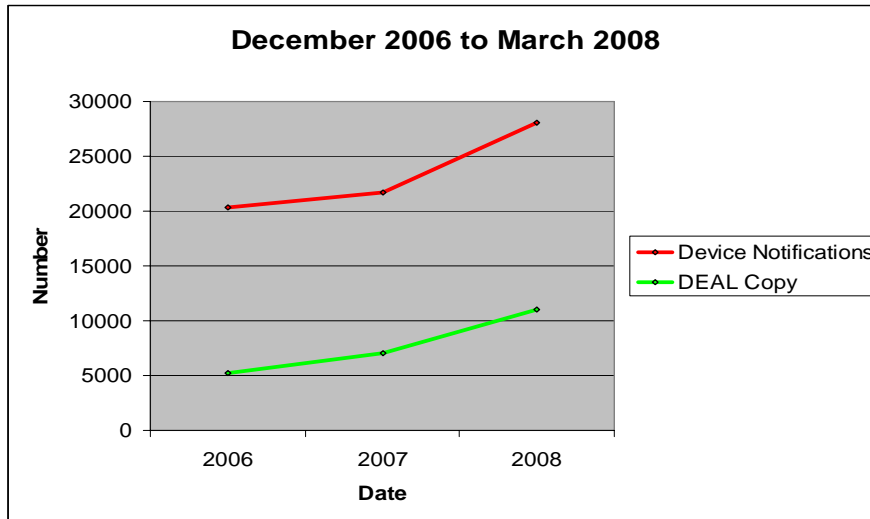
- Total notifications increased by 24% or 6643 notifications
- 40% of notifications are copied from DEAL
- Class I (low risk) devices make up the largest group and the ratio of risk classifications does not appear to have changed from March 2007
- Class III and AIMD (high risk) devices make up the smallest group
- 40% of notifications have supporting evidence. There has been an increase of 3537 evidence notifications but the ratio has not changed.

**Column graph depicting the notifications submitted between March 2007 and March 2008 based on risk classification.**



This shows there is a consistent increase in the number of notifications submitted across all risk classification over the twelve months to March 2008, Class 1 had the biggest increase.

## Graph showing the trend of the number of notifications on WAND from December 2006 to March 2008



This shows that there is a steady increase in the number of notifications on the WAND database. During the period between December 2006 to March 2007 there were **1369** new notifications submitted that grew for the twelve months to March 2008 by **6643** new notifications or an increase of 24 percent

### E-Business Queries: A Reminder

The Advisor primarily responsible for this is Rhondda Luton. Rhondda can help you with issues around your Master Password and Master ID; her email address is [rhondda\\_luton@moh.govt.nz](mailto:rhondda_luton@moh.govt.nz). The person responsible for your E-Business master account updates your user details (User IDs and User passwords).

### Change of Contact Details: Reminder to inform MOH as soon as possible

Please update your DART Advisor if there are any changes to the information we have about your company details such as address changes or name changes etc. This is a requirement to comply with current legislation. You will need to fill out a new Appendix 2 'NZ Client Details Form' and a new Appendix 3 'NZ E-Business Access Rights form' You will also find the necessary forms for transfer of sponsorship on the Medsafe website in the Medical Device section. We hope you find these useful.

### Material from WAND Workshop on Medsafe Website

All of the information presented at Medsafe's WAND Workshop in June 2007 can be found at [www.medsafe.govt.nz](http://www.medsafe.govt.nz) (under Web Assisted Notification of Devices) for your reference. You will also find an introduction to WAND and the WAND User Manual which may be useful when notifying devices onto our WAND database. Please review this information as we aim to maintain the integrity of the data kept on the WAND database. If you are still having problems please feel free to contact your DART advisor with specific questions.

### Feedback

Any feedback that you wish to supply to us about this newsletter 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.

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Medsafe