

DART NEWSLETTER

March 2008



Welcome to the 4th DART Newsletter

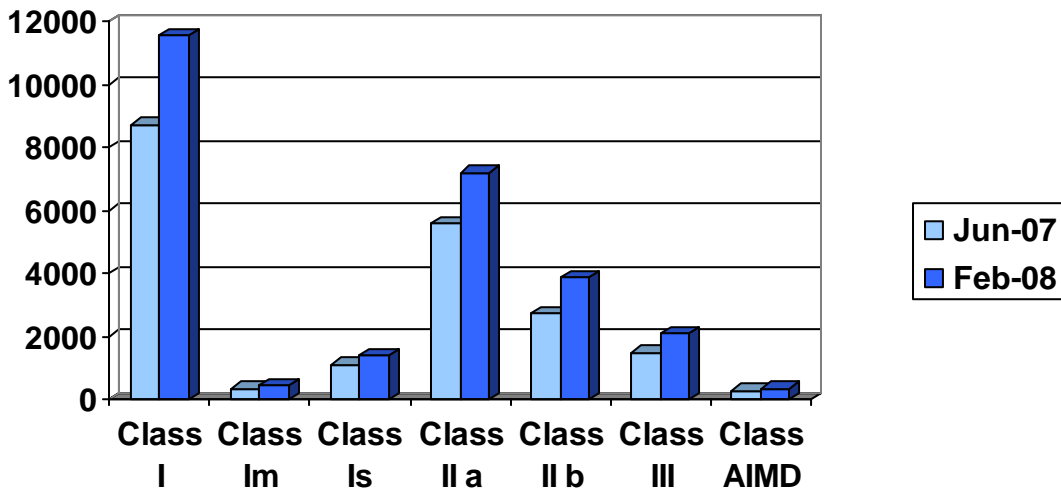
We hope you have all had a relaxing break over the holidays. We have certainly enjoyed some wonderful weather. This is usually a quieter time as sponsors have a much deserved break. However we have been busy in the background implementing the review process and improving our systems.

Update re Statistics of device Notifications on WAND

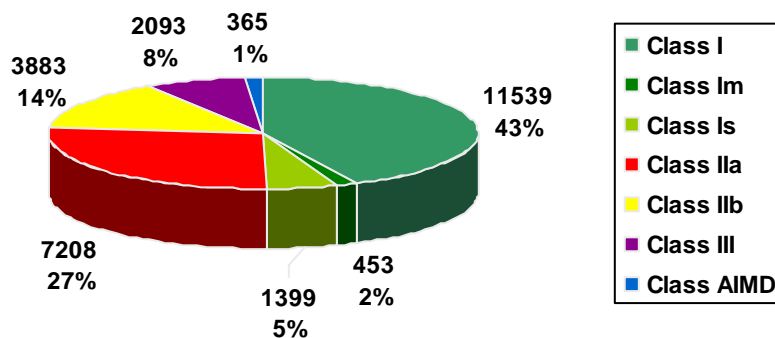
Since June last year the number of Sponsors has increased from 435 to 487; a growth of 10.7%. Correspondingly the number of WAND notifications has increased from 21720 to 26940 which is an increase of 20.8%.

WAND Growth

The following bar graph shows the number of devices notified on WAND from June 2007 compared with notifications as at February 2008. As you can see this increase has been spread over all the classes. The highest increase was in Class III at 29.3% and the lowest increase in Class IIb at 18.9%. All other classes similarly increased around 20%.



This pie graphs show the percentage of different classes of medical devices notified on WAND as at February 2008. Of interest is that the percentage of notifications in different classes has not altered significantly since June 2007.



Review of Class I Device entries in WAND

This process is going well with sponsors starting to receive feedback letters re their notifications on WAND. 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. To assist us with this task we ask that you keep your notifications on WAND current and notify your DART Advisor of any obsolete devices that you are no longer supplying.

Website Update

There have been changes to the Medsafe website in the Medical Device Section. We have been looking at the website from a sponsor perspective. Our aim was to make it more "user" friendly and easier to navigate the medical device information on the website. We welcome your feedback, positive or negative as we continually strive for improvement.

E-Business Queries:

From now all E business queries will be centralised within the DART team. The Advisor primarily responsible for this will be Rhondda Luton.

Her email address is rhondda_luton@moh.govt.nz

Changes to company name, address, agency etc

Please update your DART Advisor if there are any changes to the information we have about your company details. This is a requirement to comply with current legislation.

There are now forms available for transfer of agency from one sponsor to another on the website. These are located on the front page of the Medical Devices section of the Medsafe website. We hope you find these useful.

Helpful hints

When notifying a device in WAND please remember that the **intended purpose** is what the device is to be used for or the manufacturers intended use of the device. It is not a description of the device. If the intended purpose is inaccurate the flow on consequence is that the product may not be evaluated as a medical device, because it has no therapeutic purpose. Examples are as follows:

Wound dressing pack:

Clear Intended Purpose: This is a sterile pack that contains instruments and dressings that are to be used to clean and dress wounds.

Unclear intended purpose: Sterile pack

Intranasal splint:

Clear Intended Purpose: Nasal splints to reduce or prevent adhesions between the septum and lateral nasal wall.

Unclear Intended Purpose: Nasal splints for nose.

Feedback

Any feedback that you wish to supply to us about this newsletter 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
Team Leader
Devices
Medsafe