

## DART NEWSLETTER

August 2007



### Welcome to the 2nd DART Newsletter

#### WAND Workshop

Thank you to everyone who took time out of their busy schedules to attend the WAND Workshops held in Auckland in late June. A special thank you to sponsors who travelled long distances to come. The Workshops were very successful with good attendances at both morning and afternoon sessions. It was great to put names to faces and the DART Team members have appreciated the feedback and ongoing communication from sponsors.

#### ANZTPA Update

As you will all be aware, the Therapeutic Products and Medicines Bill is on hold. State Services Minister, Annette King says the Bill has been postponed and will remain on the Order Paper to be revisited when sufficient parliamentary support is available.

Both the Australian and New Zealand Governments remain committed to the vision of a joint trans-Tasman regulator for therapeutic products. The Agreement between the two countries remains in place, and can be ratified in the future following the passage of legislation.

The benefits to New Zealand of a joint agency include greater consumer protection, enhanced innovation, new products available in a more timely way and economies of scale in regulation.

An enormous amount of work has gone into the ANZTPA project and this will be used when considering options for the harmonisation of each country's regulatory schemes.

Health Minister Pete Hodgson says: "We will now consider the next steps, and announce them in due course. It is fair to say, however that New Zealanders, and indeed the select committee, are aware that the status quo of an unregulated market for medical devices and complementary medicines cannot remain."

#### Current Regulatory Requirements – a reminder

In the meantime, this is an opportunity to remind sponsors that although ANZTPA is now on hold, current legislation is still in force in the form of the Medicines Act 1981 and the Medicines (Database of Medical Devices) Regulations 2003.

Under these Regulations, a sponsor of a medical device in New Zealand is obligated to:

- Make a device notification on WAND within 30 working days of becoming a sponsor of that device.
- Provide specified information about the device including manufacturer details, risk classification and GMDN code.
- Make a declaration that the information provided is true and correct.
- Provide updated details within 10 days if any information ceases to be accurate or complete.
- Put procedures in place to ensure all regulations are complied with.

Registration of Manufacturer Evidence is not a mandatory requirement under current legislation. However, Medsafe encourages the lodgement of an electronic copy of evidence

with your WAND notifications. You may at some stage be required to demonstrate product safety under Section 38 of the Medicines Act 1981, and Manufacturer Evidence will go some way to achieving this.

### **DART Team Update**

Taking this message to heart the DART Advisors continue to familiarise themselves with their portfolio of sponsors. If you want to find out who your DART Advisor is, please contact us at [DART@moh.govt.nz](mailto:DART@moh.govt.nz). Also if you have any other queries please do not hesitate to email or ring 0800 DEVICE / 0800 338423

Stage 1 of the WAND project where sponsors identify and advise Medsafe of their obsolete WAND entries so they can be placed in an historical record, is still ongoing. All those sponsors who have not yet responded will shortly receive a second letter with their device list. Please take the time to review your product list for obsolete entries. A prompt response would be appreciated.

The DART team have come across a number of companies with medical devices on WAND that we have been unable to trace. The following is a list of these companies. If you have any knowledge of these companies current contact details please email us at [DART@moh.govt.nz](mailto:DART@moh.govt.nz) Your assistance is much appreciated.

1. Orthotech Orthopaedics Limited
2. Bio Service NZ Limited
3. Global Orthopaedic Technology NZ Pty Ltd
4. Honour International Trading Ltd
5. Neilmed Pharmaceutical New Zealand Pty Ltd
6. Sectra New Zealand Limited
7. Sydmed Pty Ltd
8. Surgi-Tek Limited Heat Relief
9. Amber Agencies

### **Stage 2 of the WAND Project**

We will be continuing with Stage 2 of the WAND project in the near future. This will be an opportunity to amend any errors that have occurred in the process of notifying a device or registering manufacturer evidence. In the meantime we are working with the system administrator, making minor modifications to the database to enable this to occur in an efficient and managed way.

Thank you to all the sponsors who have begun reviewing their WAND entries in detail. We have had a steady stream of questions to our advisors and it is great to see industry showing commitment to the project.

### **Feedback**

Any feedback that you wish to supply to us about this newsletter can be directed to [DART@moh.govt.nz](mailto:DART@moh.govt.nz). Your opinions and suggestions are valuable to us to determine the most useful information to provide to our medical device sponsors.