

DART NEWSLETTER

October 2007



Welcome to the 3rd DART Newsletter

DART Team is about to review all Class I Device entries in WAND

We are very pleased to announce that, within the next week, the DART Team will be starting a systematic review of all basic Class I entries on WAND. This is no small task and will be ongoing for the next several months. It will be followed by reviews of Class Im and Class Is entries and then by reviews of entries for the higher risk classes.

We will report the results back to individual sponsors in a letter which will set out the findings of the review (both positive and negative) for all the basic Class I entries lodged by that sponsor. If corrective action is required, the letter will explain what needs to be done.

By the end of the review period, we want to ensure that for each entry the:

- Correct risk classification has been entered (by applying the manufacturer's intended purpose);
- Grouping rules have been correctly applied; and
- Product described is indeed a medical device (either now under current NZ legislation or that it will be in the future when we are able to adopt the GHTF-style of regulation).

By applying this approach:

- Products (e.g.; pregnancy tests, IUCDs) that are medicines now, but under GHTF framework are devices, will remain in WAND to assist with regulatory transition in future. The sponsor will, however, be advised of the need to obtain Ministerial consent before supplying the product;
- Entries for IVDs will remain in WAND. While it is not compulsory to enter these products into WAND, notification of IVDs is encouraged to assist with regulatory transition in future;
- Products that are devices now but will become medicines under GHTF-style regulation will remain in WAND;
- Products that are "radioactive devices" will remain in WAND. Such products are not categorised as medical devices under the current legislation but would be devices under GHTF-style legislation.

Entries for products that are not used for a therapeutic purpose, and therefore are neither medical devices nor medicines, will be deleted after the sponsor has been informed. Entries lodged by sponsors who cannot be traced will also be removed from WAND and placed in an archival record.

Sponsors need to comply with the current legislation

This is a further reminder of the need to comply with the current law relating to medical devices- the Medicines Act 1981, Medicines Regulations 1984 and the Medicines (Database of Medical Devices) Regulations 2003. It is disappointing to see that some sponsors are not taking their obligations to keep the data in WAND up to date seriously enough. Please

remember that under the “WAND” 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. Please remember this includes updates of contact details or company name changes.
- Put procedures in place to ensure all regulations are complied with.

Registration of Manufacturers’ Evidence is not a mandatory requirement under current legislation. However, Medsafe encourages the lodgement of an electronic copy of evidence with WAND notifications. You may at some stage be required to demonstrate product safety under Section 38 of the Medicines Act 1981, and Manufacturers’ Evidence will go some way to helping with this.

Remember to update WAND at times of company mergers transfers and acquisitions

Please remember that the job of merging or taking over new products is **NOT** complete until you have updated WAND. We have noticed that quite a few sponsors have neglected to carry out this important safety-related action. Don’t assume “the other party” will take responsibility for the WAND update- discuss who will do it and follow through!!

A tip on how to advise Medsafe of company mergers and takeovers:

If Company A is merging with, or taking over, Company B, then both **A and B** need to send a letter to Medsafe, on company letterhead, to advise the details of the change. This is necessary to ensure that we have evidence on file that both companies are in agreement about what is occurring. The information that is kept on WAND is secure and no changes can be made without written approval from both parties.

Are you intending to cease selling medical devices?

If so please advise Medsafe so your Advisor can delete the details in WAND.

List of Missing Companies

Thank you to those who have helped us locate some of our lost sponsors!! After our last newsletter, we were able to locate several of the sponsors on our list. This issue, we have added a few more sponsors and we have also included the ones from our last issue who we have still been unable to locate. If you have any knowledge of whether these companies are still trading, or what their current contact details might be, please email us at DART@moh.govt.nz Your assistance is much appreciated.

Australasian Medical Products Ltd (NZ)	Trinity Trading Company
Oceania Medicine & Appliance Co, Ltd	PRL Medical

Astra Tech Pty Ltd	Pulsion Pacific Pty(NZ) Ltd
Orthotech Orthopaedics Ltd	Sectra New Zealand Limited
Quality and Regulatory Affairs Co Ltd	Surgi-Tek Limited NZ
Rybrooke Holdings Ltd	Heat Relief
Amber Agencies	

Obsolete WAND entries

The overall response to our request for advice about obsolete entries is still disappointingly low. Only 58% of sponsors have responded to our March mail out. Please can you ensure we can report a big improvement on this response rate in our next newsletter.

Technical problems with WAND

Unfortunately there have recently been a few technical problems accessing the live WAND database and associated delays in clearing recently submitted entries. We apologise for any inconvenience this delay may have caused. Our IT team believes the problem is now fixed and we will be monitoring this carefully.

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.