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The Manager Medical Devices
Office of Device Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

26 November, 2010

Dear Sir or Madam,

Whiteley Corporation Pty Ltd [Whiteley] is writing in response to the discussion paper concerning the Reforms in the Medical Devices Regulatory Framework dated 25 October, 2010.

Currently proposal 3(i) is unclear of the process the TGA will use to include kinds of devices. The paper states that the TGA will assess devices prior to making a decision to include the device on the ARTG and goes on to say new models will undergo assessment if the kind of device is Class IIb or above.

Whiteley believes sponsor's of new products which are currently grouped under a single entry (because they have the same sponsor, manufacturer, risk classification and GMDN code) should be responsible for notifying the TGA of their intention to market the given product. The sponsor should submit a notification along with the Declaration of Conformity, Essential Principles Checklist, Risk Assessment and a copy of the product label (or similar) via the eBusiness Services website without a full assessment by the TGA.

This approach will not only allow the TGA to know all products grouped under the one ARTG entry, helping to enhance identification of all medical devices, but won't impact on the time taken for the sponsor to be able to market the product and won't unnecessarily increase regulatory costs for the sponsor. The lack of certainty of device costs will detrimentally and unnecessarily impact the commercial risk calculations for some low volume products, or will negatively affect the competitive pricing with a major negative impact on the overall health budget, all this being caused by the indecision and imprecision of the proposed TGA amendments.

Whiteley has no issue with publishing information for all medical devices under proposal 4, so long as full formulation details are not required for chemical products. All formulated chemical products should only list ingredients if they are required for compliance with hazardous substance, scheduled poison and dangerous goods regulations. In the case of disinfectants, the active ingredient(s) should also be listed. Whiteley would support publishing similar information given in the Toratec HeartMate II LVAS example for high risk products. The level of detail required should be based on the risk classification, with higher risk products providing more information than lower risk products. The responsibility for authoring this information should lie with the manufacturer or sponsor as should ensuring the information is up to date. Rejected applications should be kept confidential between the sponsor and TGA. Rejected applications should not be published in any circumstance.

Sincerely,

Edward Wrightson
QA / QC Supervisor