TGA Therapeutic Goods Administration

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Commonwealth Department of
Health and
Family Services

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Informed Dr Sekel that the implementation is postponed to 1 Oct 1998 2:40pm 30/7/98

Dr Ronald Sekel
Portland Square Pty Ltd
St George Private Hospital Medical Centre
Suite 3, Level 5
1 South Street
KOGARAH NSW 2217

Dear Dr Sekel,

I refer to your facsimile of 15 June, 1998 and our recent telephone conversation regarding the conformity assessment of the Margron hip replacement stem and neck components for the purpose of affixing a CE Mark.

Under the recently signed Mutual Recognition Agreement (MRA)[1], the TGA will have the authority to undertake conformity assessment against the requirements of the European Medical Device Directives as required. The TGA expects that the MRA will come in to effect from 1 September, 1998, however, TGA will not receive its Conformity Assessment Body Number until around 14 September, 1998. This number is to be affixed on a product with the CE mark when a conformity assessment activity is performed by the TGA.

Once the TGA has issued the required certifications for the product, the Australian manufacturer may make a "Declaration of Conformity" and legally affix the CE mark.

If it is your intention to use TGA as your conformity assessment body, I would suggest the following steps before applying to the TGA for assessment of the products.

1. Obtain a copy of the Medical Devices Directive (93/42/EEC). The is cost around $19.50 and may be obtained from:

   Hunter Publications
   58A Gipps Street
   Collingwood Vic 3066

   Hunter Publications
   PO Box 404
   Abbotsford VIC 3064

   Tel: +61 3 9417 5361 Fax: +61 3 9419 7154

2. Identify the products that you wish to CE Mark.
3. Prepare a statement of the intended purpose of the device.
4. Familiarise yourself with the classification rules of Annex IX of the MDD and classify the products that you have chosen.

[1] Mutual Recognition Agreement in relation to Conformity Assessment, Certificates and Marking between the European Community and Australia.

5. Based on the classification, select a route to conformity from Article 11 of the Directive. Refer to the appropriate Annex and follow the defined procedure. TGA will need to be involved in the certification under any of the Annexes except where the device is fully covered by Annex VII on its own. Non-sterile, non-measuring function Class I devices are outside the scope of the MRA.
6. Please note that a technical file must be prepared for a medical device before it can be assessed and certification given to allow a CE mark to be affixed. Instructions for the preparation of a technical file are given in the Annexes of the Directive.

Once the above information has been prepared, an application by letter may be made to the TGA for conformity assessment of the device. The application should be accompanied by an application fee of $1450.00 per device. The assessment will involve a quality systems audit as specified in the MDD and may involve a design dossier review depending on the classification of the device.

The fees for this service are currently based on the fees schedule for a registrable device as attached. The dollar values are to be increased from 1 August, 1998 to reflect 100% cost recovery. Evaluation fees and audit fees will be assessed and quoted prior to the commencement of the assessment. An invoice will be raised on acceptance of the quote.

Please contact me if you require any further clarification on Ph:(02) 6232 8704 / Fx:(02) 6232 8785.

Yours sincerely,

Keith M Smith
Manager, Conformity Assessment Services-
Device Registration and Assessment Section
Conformity Assessment Branch
10 July, 1998

encl.