Australian & New Zealand
Childrens Haematology/Oncology Group

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To:
Blood and Tissues Unit
Standards and Code of GMP
Office of Devices Blood and Tissues
Therapeutic Goods Administration PO Box 100
WODEN ACT 2606

Via Email:
biologicals_consultation@tga.gov.au

Dear Sir/ Madam

Re: Submission regarding proposed standards and code of GMP for human blood and blood components, human tissues and human cellular therapies:

Perspective from Paediatric Blood and Marrow Transplant Units

Blood and marrow transplantation (**BMT**) is a high cost treatment used to cure children with cancer who will otherwise die of their underlying disease, or for children with a variety of genetic diseases where this disease can be corrected with new bone marrow. It is available in the tertiary/quaternary paediatric referral institutions across Australia and New Zealand.

On behalf of the paediatric BMT units in Australia (and New Zealand), we are providing our response to the proposed Draft Australian Code of good Manufacturing Practice Human Blood and Blood Components, Human Tissues and Human Cellular Therapies and the Draft Standards for minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapies, specifically as they apply to human Haemopoietic progenitor cells (apheresis, marrow and cord blood). Our purpose is not to highlight details of the document, which will be covered in submissions from many other groups, but to inform you that this is a process which is well underway in most Paediatric Units and some Adult Units as part of the credentialing process for the Foundation for the Accreditation of Cellular Therapy (**FACT**). The paediatric institutions have initiated this process as we know that it is a rigorous, comprehensive and internationally accepted standard. We are sure that all parts of government are keen to avoid the expense associated with unnecessary duplication.

Provision of paediatric BMT services is based within existing paediatric Oncology and Haematology Services. Such services remain heavily dependent on donated funds to supplement state and federal funding for these services. All paediatric BMT and Oncology Units are members of the Children's Oncology Group (**COG**). This is an international, collaborative, NIH funded body, based in the US, which defines state of the art therapy, deemed to be the standard of care for our patients, as recognised by our Courts. Since February 2007, COG centres performing BMT have been required to be accredited by the FACT. Our need to proceed with this was signalled in letters to the TGA (Albert Farrugia) on 13th September 2005, 19th November 2005 and 21 May 2006. We also provided a response in June 2007 to the evanescent ANZTPA.

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Almost all of the proposals from the TGA, much of the ANZTPA licensing procedure and the recent National Pathology Accreditation Advisory Council (**NPAAC**) standards are based on the FACT standards, which have been a global standard since October 2006, when the combined FACT-JACIE 3rd edition was published. The proposed requirements are based very heavily on the FACT standards. Currently[1], 175 centres are already accredited by FACT to perform BMT and many other centres have applications pending. Approved centres include the Royal Brisbane and Women's Hospital and Royal Children's Hospital, Brisbane, Bone Marrow Transplant Program and other ANZ Paediatric BMT centres are in the process of inspection. Australia already has a number of inspectors approved to inspect units to the FACT standard.

The process of FACT accreditation has all the elements required by the draft Code of good Manufacturing Practice (TGA) and NPAAC; including a rigorous quality plan and quality management systems. None of the units have been provided with government funding to pay for this process and whatever system is implemented will require a significant increase in hospital funding to support these continued quality activities. However, this cost can only increase further with duplication of services for any TGA code. Centres are already forced to use donated funds in order to afford to pay for NATA and FACT accreditation; additional TGA costs will require even more funding.

Furthermore, TGA states that it may assess overseas manufacturers of blood and tissue against the Australian standard. Of 1080 unrelated BMTs performed from 2001-2007, just over half were sourced from Australian donors.[2] The remaining cells were sourced from registries in 23 other countries. It is nonsensical to believe that the TGA is in a position to assess this volume of products. It is also a waste of resources, since most of these centres are already accredited by FACT. Any attempt to assess such registries can only lead to delay in our ability to perform BMT, often on critically ill children.

The FACT standard also assesses clinical management, as well as collection and processing, which is not present in the NPAAC or TGA documents. This reflects that FACT is a collaborative, functional, clinical group that has experience in the management of patients. On reading the TGA documents, it is clear that these documents are still heavily biased by the perspectives of drugs and blood, which are almost completely irrelevant or unworkable when dealing with human allogeneic and autologous BMT.

Our hospital administrations are slowly coming to grips with the financial consequences of needing to be FACT accredited. Additional resources are already needed by all paediatric BMT Units in order to comply with an internationally recognised level commensurate with good clinical practice. Additional requirements for NPAAC and TGA will only add further to this financial cost, and run the real risk of compromising patient care.

In summary, implementation of the code of GMP as laid out in the TGA documents:

1. Will lead to unnecessary duplication of accreditation procedures and the associated expense for centres who are already being inspected against the more stringent, globally accepted FACT Standards.

[1] http://www.factwebsite.org/ accessed Jan 25 2010
[2] ABMTRR report November 2009

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2. Still needs significant reworking, as this is based on blood and drugs, not clinical transplantation.
3. Has no value for the many overseas products which we already use
4. Does not provide the added safety of accrediting the clinical services as well as laboratory services.
5. Will vastly increase the cost of an already underfunded service.

With kind regards

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ON BEHALF OF THE BMT COMMITTEE ANZ CHOG

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