



Australia and New Zealand Corneal Society  
*The Royal Australian and New Zealand College of  
Ophthalmologists.*

11 February 2010

**Joint Submission to Therapeutic Goods Administration Consultation on Proposed standards and Code of GMP for human blood and blood components, human tissues and human cellular therapies**

Please find attached a joint submission from The Eye Bank Association of Australian and New Zealand and the Australian and New Zealand Corneal Society (the special interest group on cornea and eye banking of the Royal Australian and New Zealand College of Ophthalmologists) regarding the draft Code of GMP for Blood and Tissues, the infectious diseases standard and the specific product standard for Ocular Tissue.

Both associations represent the highest level of professional expertise in relation to eye donation, eye banking and corneal transplantation in Australia and New Zealand.

The high standards that have been developed and applied by these organisations are based on many years of accumulated experience, research, risk assessment and the application of world's-best practice. The result is an enviable record of quality, safety, efficiency and transplantation success that is unmatched in any other field of human donation or transplantation. Our two Associations are uniquely placed to comment and advise on codes of practice and infectious disease risk in relation to ocular tissue, and have also published internationally recognised Medical and Quality Standards for Eye Donation and Eye Tissue Banking.

We believe that eye donation, eye banking and corneal transplantation should be regarded in a separate category from blood and other products. This recognises the unique properties of the cornea and the specific risks to the patient of transplantation. Specifically the cornea has a surface exposed to the outside environment, as well as having several layers of cells that must remain viable if the transplant is to succeed. This has the consequence that the tissue can never be rendered completely sterile.

The attached comments on each of the relevant TGA draft documents embodies advice that allows for a workable, rational, and efficient set of codes and standards while still retaining the highest standards and principles of safety and quality that are clinically significant to ocular tissue transplantation. We believe all these comments need to be incorporated into any future documents to ensure that Australia develops a practical and responsible regulatory approach to ocular tissue donation and transplantation.

Yours sincerely,

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## **Draft Code of Good Manufacturing Practice – Human Blood and Blood Components, Human Tissues and Human Cellular Therapies.**

### **COMMENT AND JOINT SUBMISSION FROM:**

**EYE BANK ASSOCIATION OF AUSTRALIA AND NEW ZEALAND and  
AUSTRALIAN AND NEW ZEALAND CORNEAL SOCIETY OF  
ROYAL COLLEGE OF AUSTRALIAN AND NEW ZEALAND OPHTHALMOLOGISTS**

### **General Comments**

The code, as written, has areas of duplication and repetition.

It is written to address Quality issues in large scale manufacturing facilities, especially large scale blood banking. Blood donation and blood banking is a field that has a relatively high risk in regard to 1) a vector with a high potential transmissibility of disease 2) large numbers of pooled donations 3) the manufacture of products from the initial donated tissue. It is also a field that involves a large number of donations and thus encompasses substantial manufacturing facilities and large numbers of staff operating in multiple operative and support departments. None of these elements applies to ocular tissue banking. Therefore in general terms the code does not meet the needs of small scale clinical services such as Eye Banks.

*A better approach would be that which was originally proposed during the development of the biological framework – to once again have two separate codes, one for Blood and one for Tissues. This way the code can begin to address those quality system issues that are unique and relevant to smaller scale, lower risk, clinically-based operations.*

### **Clause 113**

This clause is duplicitous as it is covered by Preventative and Corrective actions, Internal audit and change management procedures, all of which are already addressed in separate clauses within the draft code. The clause also hints at a Technical Master File which may be necessary in a true materials-based manufacturing environment but not one in which human donated tissue is both the starting material and the final product.