15 December 2010

Joint Submission to Therapeutic Goods Administration Consultation on Cost Recovery Impact Statement for the Regulation of Biologicals (Human Cell and Tissue Therapy Products)

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 CRIS for Human Cell and Tissue Therapy Products.

Both associations represent the highest level of professional expertise in relation to eye donation, eye banking and corneal transplantation in Australia and New Zealand. Our two organisations together represent both the providers and the users of corneal transplant material in Australia, and therefore we are uniquely placed to provide expert comment and advice on the impact of cost recovery for the regulation of these sight restoring transplants.

The proposals within the CRIC would risk destabilising Eye Banking in Australia and subsequently jeopardise the efficient provision of corneal transplants to Australians. We strongly advise the retention of the exemption of Non-Profit Hospital Supply Units from the payment of license and inspection fees in order to prevent this situation.

Yours sincerely,

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Chair, Eye Bank Association

Professor Mark Daniel
Chair, Corneal Society
Thank you for the opportunity to provide comment in regard to the Consultation Paper: Cost recovery Impact Statement, Regulation of Biologicals.

Our professional organisations recognise that there is a cost involved in administering regulatory activities, and that there is a requirement to provide for these costs. However, the proposed charges that will be levied on Eye Banking biologicals will severely damage the ability to provide the Australian community with much needed transplants. Biologicals cannot be regarded in the same way as for profit manufacturers of pharmaceuticals or medical devices.

Currently, Non-Profit Hospital Supply Units (such as Eye Banks), are exempt under subsection 59(3) of the Therapeutic Goods Act 1989 from the payment of licence and inspection fees. This exemption recognises:

- legislation makes it an offense to derive profit from the supply of human tissue for transplant purposes. Only cost-recovery of the services associated with providing the transplant is allowed, and it is illegal to charge for the tissue itself. Indeed there is no intrinsic monetary value in the “manufactured product” (the tissue itself).
- the beneficiaries in the supply of a transplant are not the Non-Profit service providers (eg. The Eye Banks), but the recipients of the transplants.
- it is appropriate for other therapeutic industries involved in commercial activities that involve profit and high-turnover (manufactured pharmaceuticals and medical devices) to subsidise the costs involved in regulation.

The proposal to abolish this exemption under the new biological framework will have a severe impact on both the level and the extent of services provided by Eye Banks across Australia. Many Services will simply not be able to pay these charges, or they will be put under severe financial, resource and operational strain. Indeed, there is recognition of this fact within the CRIC and also by the Commonwealth Government – “To minimise the impact of the new regulation of biologicals on Non-Profit Hospital Supply Units, the Commonwealth Government has agreed to meet their direct regulatory costs for the first three years of operations of the new framework”. Unfortunately 3 years of the Commonwealth meeting these costs will not be sufficient to ensure the continued viability of the non-profit sector and continued supply of transplant tissue. The non-profit nature or the ability to finance the operations of Eye Banks will not change.

It is clear that the proposed charges in the CRIC are not linked to -

- the size of the organisation (manufacturers) supplying the biological
- the turnover (both in pure numbers and in monetary terms) of the biological provided
- donation rates (and thus the level of service provision)

In addition, the Biologicals Framework classification system upon which the level of charges is calculated is not discriminatory enough to discern the degree and time devoted to the actual regulatory process. For example – the length and breadth of audit required for a cornea (and thus the costs incurred by the TGA) is significantly less than, for example, musculoskeletal material, yet both are listed as Class 2 biologicals and both attract the same regulatory charges.

The results of abolishing the exemptions and the level of the proposed charges (without any guarantee of the Government meeting these costs beyond 3 years) will result in:

- **Closure of some Eye Banks**

Eye Banks serving their local community are vital to ensure the continued clinical efficacy, efficiency and safety of corneal transplantation within their local jurisdiction. They are of an appropriate size and have an appropriate level of service provision that is suitable to the requirements of their community. Therefore an Eye Bank, while fulfilling a vital service and performing at an appropriate level, may be small and have a low turnover. In some instances the proposed TGA charges approach
that of the total annual turnover of an Eye Bank! Income is linked to the number corneas they provide for transplant. An Eye Bank faced with a regulatory cost that approaches or exceeds all their other expenses has two options 1) Increase their service fee to a point where the service is no longer viable. 2) Be unable to pay the regulatory fee and therefore close.

E.g. An Eye Bank with a total revenue of $150,000 (income equals expenditure) that supplies 100 corneas a year. In the first year this Eye Bank would be charged at least $80,000 in regulatory fees. In order to breakeven the corneal service charge would have to rise by at least 53%. Therefore almost 50% of the total service charge would be directly attributable to TGA regulatory fees.

Closure of Eye Banks would lead to both undersupply of corneas to the community that was once well-served and an increase in cost to the community for the provision of corneas to be transported from elsewhere in Australia or imported from overseas (under Special Access schemes).

- **Prevent the establishment of new Eye Banks**
  Some smaller jurisdictions (such as Tasmania) are investigating the establishment of an Eye Bank to serve their local community (from a donation and transplant perspective). The proposed Regulatory costs now make such proposals non-viable (similar to the issues above).

- **The withdrawal of some biologicals**
  Some biologicals have an extremely small turnover in numbers and in income, and in some instances there is only one licensed manufacturer in Australia. Regulatory costs will constitute an unreasonable percentage of total service fee, and force the withdrawal of the biological from the market (to be replaced by cheaper, non-regulated imports under Special Access Schemes)
  E.g. Amniotic membrane currently attracts a service charge of $770. There is only one licensed Australian manufacturer. Annual turnover is about 30-40 items per year or approximately $30,000, and these numbers are falling. In the first year the TGA fees equate to around $70,000. This means the service fee would have to rise to around $3,300 per service with regulatory fees directly contributing 70% of this cost! Already burdened by the indirect costs involved in maintaining a license for this product, it then becomes cheaper and more efficient to import non-licensed product under Special Access Schemes (as has happened in the past when there was no licensed Australian manufacturer).

- **The stifling of innovation and the introduction of new techniques**
  Many newer techniques require large capital investments or venture capital to be realised and within biologicals (especially Eye Banking) are unlikely to ever recoup these costs in service fees. This is because of low turnover coupled with high costs. Regulatory fees at the proposed levels will make the introduction of many new innovations and technological advancements untenable for non-profit organisations such as Eye Banks.

In summary:

In order to prevent destabilisation and harm to Eye Banking and risk jeopardising the provision of corneal transplants to Australia, the exemption of Non-Profit Hospital Supply Units (e.g. Eye Banks) from the payment of license and inspection fees (TGA regulatory fees) **must** remain. It is simply not feasible for any Australian Eye Bank to be able to pay these charges now or in the future.