NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Multiple Technology Appraisal (MTA)

Immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85)

RESPONSE TO ASSESSMENT REPORT

From: [redacted] [redacted] on behalf of The Efficacy and Safety of PRescribing In Transplantation (ESPRIT) Group

As an independent group, the ESPRIT Group (www.esprit.org.uk) does not advocate any particular product and our opinions, recommendations and activities are all our own. As such we could not contribute to NICE's assessment of the *comparative* efficacy and cost-effectiveness of individual immunosuppressants included in the MTA, which forms a key part of the current Assessment Report. However, where we feel that we have an important contribution to make is in relation to the efficacy and safety implications of the introduction of generic versions of these immunosuppressant medications. This formed the basis of our original submission and we hope that the final NICE guidance piece does include provision for our recommendations.

In summary, we recommended establishment of a 'Good Generic Practice' for immunosuppressants used in the very specialist transplant population. Generics are licensed on the basis of bioequivalence in healthy volunteers, which does not necessarily translate into clinical equivalence in individual patients, as witnessed by various examples included in our original submission and later reinforced by subsequent research by the ESPRIT Group (*in press*). For this reason we urged NICE to issue good practice guidance that immunosuppressants for transplant patients should be prescribed and dispensed by brand and switches should only be carried out in the specialist hospital setting with appropriate monitoring. Not only can this help ensure the efficacy and safety of use of generic immunosuppressants, it can also be cost-effective; inadvertent switches can lead to unwanted side effects, acute rejections, hospitalisations, retransplants and returns to dialysis, all with associated costs.

Finally, at a time when the campaign to encourage increased organ donation is fully underway, and there are patients dying on the waiting list for organs, it would seem expedient not to do anything which could put these precious commodities at risk.