More stringent evaluation on the use of generic medications in thoracic transplantation

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A closer look at regulatory and clinical concerns with generic immunosuppression medications in thoracic transplantation is required, according to an educational advisory by the International Society for Heart and Lung Transplantation (ISHLT) in the July 2009 issue of The *Journal of Heart and Lung Transplantation*.

Thoracic transplant patients require immunosuppressant medications that are classified by regulating agencies around the world as "critical dose drugs" due to an increase in risk of harm from comparatively small differences in dose or concentration. These "critical dose drugs", however, do not receive any additional testing or evaluation in transplanted patients before being approved by worldwide regulating agencies.

Approval for brand names drugs is only given after careful testing by regulatory agencies. These drugs are studied in a stringently controlled format in patients who have the condition for which the drug is to be prescribed. The process for generic drug approval is different. Generic drugs are required to have the identical active ingredients as the brand product in the same strength and rate and extent of absorption. These products are then tested on a small number of healthy volunteers.

Evaluating healthy volunteers does not adequately represent the challenges faced in prescribing immunosuppressant medication in

transplant recipients. Many times, transplant recipients are far from healthy and face the challenges of chronic disease, effects of drug therapy on non-translated organs, and interacting medications.

"A presumably bioequivalent generic product when applied in the setting of transplantation often demonstrates a different and unanticipated pharmacokinetic profile. This issue is of special concern in patients prone to graft rejection and especially in children", said Dr. Patricia A. Uber, Assistant Professor of Medicine at University of Maryland School of Medicine and the lead author of this advisory.

The ISHLT Board of Directors assigned a group of transplant practitioners from various countries to develop this educational advisory to inform transplant practitioners about generic immunosuppression.

Key recommendations in the educational advisory include:

1. Education of the patient to inform the health care professionals caring for them if their immunosuppressant medication has been changed

2. Education of other prescribers of the concerns regarding a switch to a generic immunosuppressant

3. Awareness that heightened surveillance following a change in critical medication to avoid adverse effects such as toxicity or rejection

4. Advocacy surrounding notification of an automatic generic substitution from the dispensing agencies to the prescriber

More information: The article is "Generic Drug Immunosuppression in

Thoracic Transplantation: An ISHLT Educational Advisory" by Patricia A. Uber, PharmD; Heather J. Ross, MD; Andreas O. Zuckermann, MD; Stuart C. Sweet, MD; Paul A. Corris, MD; Keith McNeil,MD; and Mandeep R. Mehra, MBBS. It appears in The Journal of Heart and Lung Transplantation, Volume 28, Issue 7 (July 2009) published by Elsevier. www.jhltonline.org/

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