

# ESPRIT

## Efficacy and Safety of PRescribing In Transplantation

### Guidance on Management of Repatriation and Immunosuppressant Switches in Transplant Patients

August 2015

#### Background

The ESPRIT Group is a totally independent group of multidisciplinary healthcare professionals, dedicated to the safety and well-being of transplant patients ([www.esprit.org.uk](http://www.esprit.org.uk)). As part of repatriating immunosuppressant prescribing from primary care back to secondary care, many UK transplant units have been switching from branded to generic immunosuppressants, and more units will be doing so in the future. However, whilst a Framework on repatriation of transplant patients was issued by NHS England in September 2014, there has been no central collation of actual results to facilitate shared learnings, especially in relation to switches. Following pilot research in 2013 on patient perspectives on such switching, ESPRIT extended its research in 2014 and undertook a direct study via specialist pharmacists in transplant units, to investigate in detail both the process and outcomes of switching.

The results of this research revealed significant variations in how different units approached the task in hand, especially in terms of patient management and monitoring during switches. However, some key aspects of best practice were also highlighted. The ESPRIT Group therefore convened a group of experts with direct experience of managing repatriations and immunosuppressant switches and agreed some best practice principles. It is hoped that this informed guidance will help optimise switches going forward, in the interests of patient safety and improving the experiences of patients and healthcare professionals alike.

#### Scope of Guidance

The general guidance principles of best practice gained from units' experiences cover both the repatriation and switching of patients from originator brands of immunosuppressants. The specific **monitoring** recommendations applies to switches from branded ciclosporin and tacrolimus to generic alternatives.

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### Key Considerations and Recommendations

#### **Overall Management**

- Where repatriation is taking place, carry this out first, get the patient's confidence and then move onto the switching programme
- Plan the necessary investment up-front. As part of this agree the mechanism(s) for provision of patients' immunosuppressants depending on local circumstances, including:
  - Direct from the hospital pharmacy
  - Satellite pharmacy on site – some third party providers may also facilitate pick-up from local branches
  - Home delivery – via contract supplier or some units have arranged their own Trust-owned home delivery services
  - FP10HPs
  - Royal Mail
- Allow patients a choice of how they receive their drugs, especially if they live far from the unit
- Establish a local drug delivery contingency plan in case of any failures in supply
- Have a designated individual to manage the whole switching process and be the main contact point for the patients, ideally a clinical pharmacist
- Have a mechanism for rapid response in case of patient problems after switching, including emergency contact details (telephone numbers, email addresses)

#### **Communications about Switches**

- Take the time to approach the patients carefully, warn them up front about the proposed change and involve them in the process
- Communicate both in written form and verbally– and call them at home to arrange the switch so that patient's existing supplies of original brand can be properly assessed
- Ensure consistent messaging from different members of the transplant team if at all possible – having the signatures of both pharmacy and medical colleagues on letters to patients can help reinforce unity and enhance patient confidence
- Be completely truthful as to the reasons behind switching to generic immunosuppressants
- Inform patients of the most likely adverse effects that they may experience
- Inform and involve the local patient associations as they can provide important support and reinforcement/ reassurance to the patients
- Write to relevant GPs and community pharmacists and spell out exactly what they need to do in future – e.g. keep a transplant patient's immunosuppressants listed on their records to maintain a holistic picture of their overall medications, but flag the immunosuppressants as not for prescription by the practice
  - Make sure you let GPs know after repatriation has happened, rather than before, so they know exactly when their immunosuppressant prescribing responsibility ends

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- Make sure you let GPs know after a switch has happened so that if a patient reports adverse effects from the new brand to the GP, they will be able to advise the patient appropriately
- Ask the GP to record the brand of immunosuppressant on their prescribing system in case the patient requests an emergency supply from the GP surgery

### **Managing the Switches**

- Be appropriately selective from the start - exclude any unstable patients from the switch programme e.g. those with current active rejections, failing grafts, concomitant issues or conditions, active infections etc. They can always be followed up later to reassess suitability
- Accept that some patients do not want to be switched and shouldn't be forced to do so
- Avoid wastage of medication and aim to switch the patient when they are near to finishing their current supply of originator brand
- In terms of **monitoring** the effects of switches, the **ideal procedure** to follow, based on experience in practice, is:
  - If patients' levels have been variable it may be prudent to carry out a baseline levels assessment immediately pre-switch, assuming this is practically feasible
  - Arrange for trough blood levels and U&E to be measured 7-14 days after switch, to assess the potential need for dosage change of the generic immunosuppressant
  - If immunosuppression or creatinine levels are considered to be outside the normal range of variability for the individual patient, repeat these measurements or amend the dosage accordingly and repeat again after another 7-14 days
  - Call patients after switch to check progress and ask about any side effects
  - Accept that a small proportion of patients may need to be switched back to their original brand, mostly as a result of side effects
  - With calcineurin inhibitor switches, make clear to the patient that they must continue taking the same generic brand of their immunosuppressant and not to mix brands

If the whole process is managed effectively in this way, the dedicated patient focus involved not only helps ensure patient safety but is also likely to build patient trust and benefit ultimate outcomes.

### **Contributors**

The following were involved in the compilation of this guidance and the ESPRIT Group would like to express sincere thanks to them for their input of experience:

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