Reviewer's report

Title: Inability to Achieve a Therapeutic Dose of Tacrolimus in a Pediatric Stem Cell Transplant Patient due to Generic Substitution

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Reviewer: Domenico V Delfino

Reviewer's report:

The report from Madian et al. entitled "inability to achieve a therapeutic dose of tacrolimus in a pediatric stem cell transplant patient due to generic substitution" is an interesting case report that highlights differences between brand name and generic formulation of tacrolimus in a pediatric patient. Authors appropriately describe the case and draw the reasonable conclusion that the generic formulation of tacrolimus did not work as well as the brand name formulation in this particular case. I agree with the authors' conclusions, however I have only a concern regarding the duration of generic tacrolimus treatment. In figure 1 it is shown that blood tacrolimus concentrations decrease under the minimum effective concentration. This happened few times also when the patient is back to the brand name tacrolimus treatment. My question is: if the treatment with the generic formulation would be prolonged as was the treatment with brand formulation, is there any possibility to achieve a concentration of the drug in the therapeutic range? In other words, it may be the time, and not the dose, the parameter to be taken in consideration to achieve therapeutic blood concentrations of the generic formulation? Authors should comment on this issue.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests