Reviewer’s report

Title: Pharmacokinetics comparison of two pegylated interferon alfa formulations in healthy volunteers

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Reviewer: Hesham Al-Sallami

Reviewer's report:

The authors of the article titled "Comparison of the pharmacokinetics of two peginterferon alfa formulations in healthy volunteers" present a PK comparison of two peg-interferon alpha formulations in healthy volunteers.

The article is methodologically-sound. However, it is not clear why the study was done and whether it has relevant implications for readers of this journal.

The study appears to be a bioequivalence study. If this is the case then it would be of little interest to the readership of this journal. If not, and indeed the two products compared have varying exposure-response relationship, then the exposure-response needs to be assessed (in patients instead of healthy volunteers) in order to provide clinical relevance for the readers.

The discussion of pegylation in the Intro added confusion because it wasn't relevant to the aims of this study.

As a BE study, the methodology is sound apart issues with the duration of sampling. Sampling was carried out for 14 days which exceeds 4 x the proposed half-life of the drug yet the analysis was not able to capture the full AUC. This may suggests that sampling should have been extended for longer than 14 days.

Regards and best wishes.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes
Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
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I am able to assess the statistics

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Needs some language corrections before being published

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