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PEER-REVIEW REPORT

Name of journal: *World Journal of Hepatology*

Manuscript NO: 110726

Title: Generic versus brand forms of direct acting antivirals for hepatitis C virus treatment in Egyptian children

Provenance and peer review: Invited Manuscript; Externally peer reviewed

Peer-review model: Single blind

Reviewer's code: 08691545
Position: Peer Reviewer
Academic degree and professional title: MD, PhD
Reviewer's Country/Territory: China
Author's Country/Territory: Egypt

Manuscript submission date: 2025-06-17
Reviewer chosen by: Hong-Xin Jiang
Reviewer accepted review: 2025-06-26 03:37
Reviewer performed review: 2025-07-01 10:39
Review time: 5 Days and 7 Hours

Content to be reviewed	Does the manuscript's content fall within the scope of the journal? **Yes** Is there any Key Word that is not included in the manuscript title? **Yes** Do authors' affiliations correspond to the content of the manuscript? **Yes** Does the Abstract contain the contents of each part of the manuscript (IMRaD)? **Yes** Are the Key Words complete? **Yes**

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	Is the content of the Introduction adequate? **Yes** Is the content of the Materials and Methods complete? **No** Is the description of the experiments clear and complete? **No** Are the experimental data presented in the manuscript's biostatistics content reliable? **No** Are the experimental data of the Results true and reliable? **Not Applicable** Are the quality and resolution of the images up to standard? **Not Applicable** Do the selection and design of the figures and tables follow the principles of necessity and clarity? **Not Applicable** Is there any duplication between various parts of the manuscript and between the main text and the content presented in the figures and tables? **No** Are the figures and tables numbered consecutively in the order in which they appear in the manuscript? **Yes** Is the content of the Discussion reasonable? **Not Applicable** Is the Conclusion reasonable? **Yes** Are all references necessary and reasonable? **Yes** Do authors omit important references? **No** Are all references related to the topic of the manuscript? **Yes** Do authors only cite their own earlier publications? **Yes** Is the manuscript's text correct, concise, and clear? **No** Will the manuscript's content be of interest to readers? **Yes**

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	Are additional experiments needed for the study? **No** Does the research scope comply with ethics? **Yes**
Scientific quality	Grade C (Good)
Novelty of this manuscript	Grade C (Good)
Creativity or innovation of this manuscript	Grade D (Fair)
Scientific significance of the conclusion in this manuscript	Grade B (Very Good)
Language quality	Grade B (Very good)
Does this manuscript describe a study of the existing knowledge system?	Yes
Does this manuscript report a revolutionary innovation?	No
Does this manuscript report an unconventional innovation?	No
Conclusion	Major revision
Re-review	No
Peer-reviewer statements	Peer-Review: Anonymous
	Conflicts-of-Interest: No
Are your review comments generated by AI tools?	

SPECIFIC COMMENTS TO AUTHORS

The study focused on the difficulty of use high-priced original drugs in areas where the treatment of HCV in children is relatively backward and resources are limited. The study compared the efficiency of using generic drugs or marketed drug for treating hepatitis C virus in children, in Egypt. The finding of this study suggested that Ledisbuvir has a comparable treatment effect in pediatric patients infected with HCV.

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However, the design of this study, the presentation, and data analysis remains some issues I listed as follows:

(1) Although the sample size covered 116 children, the grouping was uneven (43 cases in the generic drug group and 73 cases in the original drug group). Please provided the raw data in relation to each patient before and after treatment of respective drugs in supplemental files, which could help understanding and re-purpose of these clinical data. The lack of such data weakens the convincing conclusion of the conclusion. As stated, “Group comparisons were performed using Student’s t-test or Mann-Whitney U test and Pearson chi-square or Fisher exact test for continuous and categorical variables respectively.” however, By which data type and by which one of statistical methods you specifically used for Tables 1, 2 and 3 are not specified.

More specific comments:

a\ Table 1 indicates an age range of 7-18 years, which contradicts the enrollment criteria stated in the article, requiring participants to be ≥12 years old or weigh >35 kg. Supplement the weight data of 7-year-old patients or explain the basis for their compliance with the standard.

b\The data of "related comorbidities" in Table 1 contradict the sample size within the group, and the percentage seems to be calculated according to the total number of people with related comorbidities, which is easy to cause misunderstanding. The erroneous data here will affect the authenticity of the conclusions of the article on comorbidities

c\ In the baseline investigations, the total bilirubin and INR of the patients in the generic drug group were slightly higher, although they were within the normal range, but it was necessary to clarify whether there was a potential difference in liver function and whether it had an impact on treatment response. Continuous variables such as age, liver function indexes, etc., some of which are Mean±SD and some are Median (IQR), should

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be described in a unified manner or with reasonable explanations.

d\In the “Degree of hepatic fibrosis Fibroscan” in Table 2, the total sample size of Harvoni group is 73, while the data sample size in the table is only 72 (59 + 13)

e\The percentages in Table 3 were calculated based on the total number of people who had adverse reactions. This is not the incidence within each group, which is easy to mislead readers to misestimate the true side effect rate of the Harvoni group.

2\ The author repeatedly emphasized the "cost advantage of generic drugs", but the full text did not provide relevant data, such as the specific price of generic drugs, treatment cost savings during the treatment course, etc. It is suggested to supplement comparative data or cases to support the conclusion.

3\The table title is too long, and it is recommended to simplify the repeated expression, such as deleting the redundant “patients who received...”.

4\The article only states “institutional approval”, please supplement the specific ethics No# in the “PATENTS AND METHODS” section.