Reviewer's report

Title: Pharmaceutical quality of seven generic Levodopa/Benserazide products compared with original Madopar(R) / Prolopa(R)

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Reviewer: Salvatore Amoroso

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The Manuscript “Pharmaceutical quality of seven generic Levodopa/Benserazide products compared with original Madopar/Prolopa” by Urs E Gasser, Fischer Anton, Jan P Timmermans and Isabelle Arnet compares the pharmaceutical quality of some generic levodopa/benserazide hydrochloride combination products available in Germany with the original product by Roche.

Several characteristics have been evaluated, such as colour, appearance of powder (for capsules), disintegration and dissolution, mass of tablets and fill mass of capsules, content, identity and amounts of impurities. Authors conclude that each of the generic products (seven) that have been taken into consideration had 1 or 2 parameters outside the specification. They conclude that these deviations, that generally are not notified, could affect the pharmacokinetics of drugs, with important clinical consequences if a switch from the original to the generic drugs occurs during a long term therapy.

Discretionary Revisions

The paper is well written and it deals with a very interesting issue, the interchangeability between a brand name and a generic equivalent, since the conversion from brand name to a generic equivalent is somehow conflicting. Authors provide several chemical evidences that lead to carefully use a generic drug.

1-Do authors have any data concerning the pharmacokinetics of the investigated generic drugs in patients and/or healthy volunteers?
2-Do they consider this issue a critical point? If possible authors should further discuss this issue.

Level of interest: An article whose findings are important to those with closely related research interests

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'