Author's response to reviews

Title: Comparison of two recombinant erythropoietin formulations in patients with anemia due to end-stage renal disease on hemodialysis: A parallel, randomized, double blind study.

Authors:

Jorge F Perez-Oliva (jfpolivd@infomed.sld.cu)
Martha Casanova-Gonzalez (martahaf@jagua.cfg.sld.cu)
Idrian Garcia-Garcia (idrian.garcia@cigb.edu.cu)
Pedro J Porrero-Martin (pedro.porrero@cigb.edu.cu)
Carmen M Valenzuela-Silva (carmen.valenzuela@cigb.edu.cu)
Tairi Hernandez-Montero (tairi.hernandez@cnic.edu.cu)
Marcia Lagarde-Ampudia (marciala@infomed.sld.cu)
Yuri Casanova-Kutsareva (yuri.casanova@cigb.edu.cu)
Yisel Avila-Albuerne (yisel@cencec.sld.cu)
Alicia Vargas-Batista (alicia@cencec.sld.cu)
Haileen Bobillo-Lopez (hailen.bobillo@cigb.edu.cu)
Raul Herrera-Valdes (insnef@infomed.sld.cu)
Pedro A Lopez-Saura (lopez.saura@cigb.edu.cu)

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Response to reviewer’s comments

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Dr. Schellekens think that the paper is now publishable and most of his comments have been taken in account. Major, minor and discretionary revisions are not necessary this opportunity. Just two remarks still. These are the answers:

1. We consider that the conclusion is clear and correct. As we replied previously we have followed a strategy of demonstrating molecular and pharmacological similarity, and then to introduce the product and pursue a suitable monitoring of efficacy, safety, and immunogenicity of EPO.

2. Certainly, is possible the interchangeability of biological – derived products without a complete dossier. For instance, in the case of IFN beta we do not refer to the different brands but to the case of Avonex, where FDA registration was presented with the clinical trial done with the product manufactured in an installation different of the registered, only based in a bioequivalence study. Similarly, for growth hormone this was by a bioequivalence trial, and not by a complete dossier. Please, see reference Nº 9 in the manuscript.