Reviewer's report

Title: Active Post-Marketing Surveillance of the Intralesional Administration of Human Recombinant Epidermal Growth Factor in Diabetic Foot Ulcers

Version: 1 Date: 1 June 2013

Reviewer: Luigi Uccioli

Reviewer's report:

Referee Active Post-Marketing Surveillance of the Intralesional Administration of Human Recombinant Epidermal Growth Factor in Diabetic Foot Ulcer

The authors evaluate the effectiveness and safety of the intralesional administration of human recombinant epidermal growth factor (hrEGF) for treatment of diabetic foot ulcers in a post-marketing surveillance.

Some concerns arise from the manuscript:

First of all it should be clearly expressed that all the references come from the same group and that the approved regulatory come from the same country.

The authors report the outcomes: complete granulation, amputations, adverse effects, complete healing and relapses of the whole group analyzing the influence of single factors as characteristics of the ulcers (simple, complex, calcaneal) or grading according to Wagner classification (from 1 to 5) or presence or not of peripheral arterial disease. In addition they pool together patients treated by 25 or 75 ug.

This way to present the data is confusing and the reader does not get the real advantage of using EGF in the different ulcers. Probably all the results should be much more clear if it could possible re-classify the ulcers according the university of Texas wound classification and evaluate the outcomes according to the different classes and grades, deviding also the groups of patients according to the dosage use.

A final consideration is related to the major outcome. 'complete healing' is a subjective parameter and in the absence of a control group it could be debated wether can be used to establish the efficacy of a therapeutic approach. On the contrary complete healing, amputation and death are objective outcomes and therefore my suggestion is to use these outcomes to highlight the therapeutic potentiality of hrEGF.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the
statistics.

Declaration of competing interests:

No