Reviewer’s report

Title: The weight lowering effect of sibutramine and its impact on serum lipids in cardiovascular high risk patients with and without type 2 diabetes mellitus - an analysis from the SCOUT lead-in period

Version: 3 Date: 25 September 2009

Reviewer: Zbigniew Gaciong

Reviewer’s report:

In their manuscript the Authors reported data on changes in lipid profile in a group of subjects during run-in period of SCOUT trial. They measured lipid profile in 10 742 high cardiovascular risk, obese subjects before and after 6 weeks of sibutramine treatment and life-style modification. The major finding in their study was that changes in lipid profile were significantly lower in the group of diabetic patients, also after correction for a degree of BMI reduction. They also identified factors associated with the response to intervention (gender, smoking) and influence of concomitant therapy with statins and fibrates. This report includes the highest number of subjects ever recruited in a single clinical trial with sibutramine however from the relatively short term of observation and not placebo-controlled.

The aim of the study is well defined and the manuscripts fulfills all “technical” criteria (methods, statistics, language, presentation of the data etc.). However, this is one of the series of papers which uses data collected during initial period of SCOUT trials. The same group of authors have already published papers on blood pressure, bilirubin, tolerability, cardiovascular responses, thus dismembering results to multiply number of publications.

The paper can be published after minor essential revisions listed below:

In the Methods section they wrote that treatment lasted 6 weeks while in Discussion 4 weeks of sibutramine administration was mentioned.

In the Discussion they missed the study by CA Dujovne et al (Effects of sibutramine on body weight and serum lipids: A double-blind, randomized, placebo-controlled study in 322 overweight and obese patients with dyslipidemia. Am Heart J 2001; 142: 489-97) which should be acknowledged.