sanofi aventis

Dr Eric Abadie
Chairman of CHMP
European Medicines Agency
7 Westferry Circus
Canary Wharf
London E14 4HB
United Kingdom

Chilly-Mazarin, 22 May 2008

Re: Withdrawal of DuoPlavin® (fixed-dose combinations tablets of 75 mg clopidogrel / 75 mg acetyl salicylic acid and 75 mg clopidogrel / 100 mg acetyl salicylic acid) marketing authorisation application
DuoPlavin®: EMEA/H/C/000874

Dear Dr. Abadie,

I would like to inform you that, at this point of time, Sanofi Pharma Bristol-Myers Squibb SNC has taken the decision to withdraw the application for the marketing authorisation for DuoPlavin® (fixed-dose combination tablets of 75 mg clopidogrel / 75 mg acetyl salicylic acid and 75 mg clopidogrel / 100 mg acetyl salicylic acid), which was intended to be used as substitution therapy replacing clopidogrel and acetyl salicylic acid as separate compounds for the approved indication of prevention of atherothrombotic events in acute coronary syndrome (non-ST segment elevation acute coronary syndrome and ST segment elevation acute myocardial infarction).

This withdrawal is based on the CHMP's request regarding the need to document bioequivalence based on clopidogrel plasma levels in accordance with the Questions & Answers on the Bioavailability and Bioequivalence Guideline (EMEA/CHMP/EWP/40326/2006). To address the CHMP's request Sanofi Pharma Bristol-Myers Squibb SNC intends to perform a new bioequivalence study measuring plasma levels of clopidogrel parent compound. However, the results of that study will unfortunately not be available in the timelines defined by the Centralised Procedure.

We reserve the right to make further submissions at a future date for this fixed-dose combination of clopidogrel and acetyl salicylic acid in the approved indication.

I agree for this letter to be published on the EMEA website.

Yours sincerely,

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