PHARMACEUTICAL
INDUSTRIES
EUROPE BV

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

Hoofddorp, 23 March 2010

Subject: **Withdrawal of Repaglinide SUN 0.5mg/ 1mg/ 2mg film-coated tablets**
Procedure number: **EMEA/H/C/1145//0000**

Dear Sir Abadie,

I would like to inform you that, at this point of time, Sun Pharmaceutical Industries Europe B.V. has taken the decision to withdraw the application for Marketing Authorisation of Repaglinide SUN 0.5mg/ 1mg / 2mg film-coated tablets, which was intended to be used for "the treatment of patients with type 2 diabetes (Non-insulin-Dependent Diabetes Mellitus (NIDDM) whose hyperglycaemia can no longer be controlled satisfactory by diet, weight reduction and exercise. Repaglinide is also indicated in combination with metformin in type 2 diabetes patients who are not satisfactorily controlled on metformin alone. Treatment should be initiated as an adjunct to diet and exercise to lower the blood glucose in relation to meals".

This withdrawal is based on the following reason:
Sun Pharmaceutical Industries Europe B.V. has decided to discontinue this application due to the company's marketing strategy.

At the present time, there are no ongoing clinical trials with Repaglinide Sun 0.5mg, 1mg, 2mg tablets, and there are no future plan for development of the product.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

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