

Merck Sharp & Dohme (Europe), Inc.  
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Director  
Regulatory Affairs – Europe



To: Dr. Abadie  
European Medicines Agency  
7 Westferry Circus  
Canary Wharf  
London E14 4HB  
United Kingdom

Brussels, November 7, 2011

**Subject:** Withdrawal of JANACTI (Sitagliptin and Pioglitazone 100/30 mg and 10/45 mg, film coated tablets) and related trade names  
EMA/H/C/002394/002519/002520/002521/0000

Dear Dr. Abadie,

I would like to inform you that, at this point of time, Merck Sharp and Dohme Ltd. has taken the decision to withdraw the application for Marketing Authorisation of JANACTI (sitagliptin and pioglitazone 100/30 mg and 100/45 mg fixed-dose combination tablets) and related trade names, which was intended to be used for the treatment of adult patients with type II diabetes mellitus.

This withdrawal is based on a review of the regulatory and commercial prospects for the fixed-dose combination product. There are currently no on-going clinical trials with the fixed-dose combination.

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 EMA website.

Yours sincerely,

