



Pharma B.V.

Dr Tomas Salmonson  
European Medicines Agency (EMA)  
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London E14 4HB  
UK

11 July 2013

**Subject:** Withdrawal of the Effentora (fentanyl buccal tablets, 100 µg, 200 µg, 400 µg, 600 µg and 800 µg) **Type II variation category C.I.6.a** to extend the therapeutic indication in the treatment of breakthrough pain in adults who are already receiving maintenance opioid therapy for chronic persistent pain - **EMEA/H/C/833/III/018**

Dear Dr. Salmonson,

***For the withdrawal of Type II variation linked to an extension of indication for a medicinal product already authorised***

I would like to inform you that, at this point of time, Teva Pharma B.V. has taken the decision to withdraw the application for the extension of the therapeutic indication for Effentora (fentanyl buccal tablets, 100 µg, 200 µg, 400 µg, 600 µg and 800 µg) in the treatment of breakthrough pain in adults who are already receiving maintenance opioid therapy for chronic persistent pain.

The withdrawal is based on the following reason:

Teva Pharma B.V. has taken this decision based on the CHMP's view that the proposed extended indication would mean the introduction of a new treatment paradigm and that data so far are not sufficient to address CHMP's concerns.

This decision will not have consequences for patients enrolled in any ongoing Teva-sponsored Effentora. study at this time.

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

**Registered office**

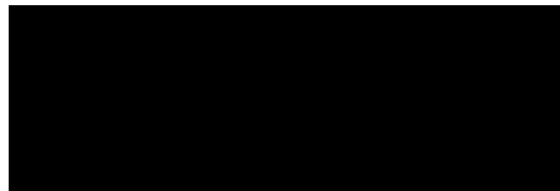
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[www.tevapharm.com](http://www.tevapharm.com)

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Bank: ABN AMRO Bank N.V.  
Account number EUR: 240653602; IBAN NL69ABNA0240653602  
Account number GBP: 242135501; IBAN NL35ABNA0242135501  
Account number USD: 242135528; IBAN NL82ABNA0242135528

I agree for this letter to be published on the European Medicines Agency website.

Yours sincerely,



Dr Ekkehard Baader  
Head, European Regulatory Affairs,  
Branded Products  
Research and Development

