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## Global Research & Development

19 November 2008

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

**Subject: Withdrawal of Type II Variation EMEA/H/C/202/II/45 for Viagra (sildenafil), 50 mg, film-coated tablets**

Dear Dr Abadie,

**For the withdrawal of a Type II variation applying for a change in the legal status of Viagra 50 mg film-coated tablets from “medicinal product subject to medical prescription” to “medicinal product not subject to medical prescription”**

I would like to inform you that, at this point of time, Pfizer has taken the decision to withdraw the ongoing application for a change in the legal status of Viagra 50 mg film-coated tablets.

The withdrawal of the variation application is being requested in order to fully consider comments from the CHMP, recognising that there were some concerns regarding the proposed supply of Viagra 50mg tablets without a prescription in the pharmacy setting across the EU. The withdrawal will enable evaluation of further information and additional data that may be required to allow any future assessments under the EMEA centralised procedure.

We reserve the right to make further submissions at a future date.

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

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Yours sincerely,

Worldwide Regulatory Strategy – EU  
Pfizer Ltd



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