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Dr. Abadie

European Medicines Agency (EMA)
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Brussels, November 5th 2010

**Subject: Withdrawal of Zenhale, mometasone furoate/formoterol fumarate, 50/5, 100/5 or 200/5 micrograms, pressurised inhalation, suspension
EMA/H/C/001217/0000**

Dear Dr. Abadie,

I would like to inform you that, at this point of time, Schering-Plough Europe has taken the decision to withdraw the application for the Marketing Authorisation of Zenhale, mometasone furoate/formoterol fumarate, 50/5, 100/5 or 200/5 micrograms, pressurised inhalation, suspension which was intended to be used for long-term, twice-daily maintenance treatment of asthma, including reduction of asthma exacerbations, in adults and children 12 years of age and older.

This withdrawal is based on the following reason: Schering-Plough Europe is withdrawing the application since, after the CHMP had assessed the company's responses to the List of Outstanding Issues, there remain outstanding questions that require more time to address than is allowed within the centralized procedure.

This withdrawal does not have any consequences on ongoing trials or on compassionate use programme.

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,