

[REDACTED]
European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

3 April 2018

Subject: Qtern (saxagliptin/dapagliflozin fixed combination medicinal product) 5mg/10mg film-coated tablets - Withdrawal of EMEA/H/C/004057/II/0013

Dear [REDACTED]

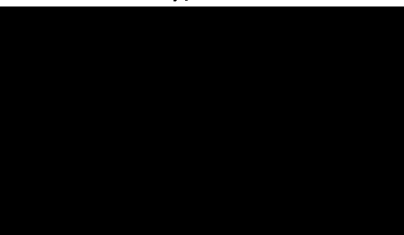
I would like to inform you that, at this point of time, AstraZeneca has taken the decision to withdraw the application EMEA/H/C/004057/II/0013 for a new indication to the marketing authorisation for Qtern (saxagliptin/dapagliflozin fixed combination medicinal product), 5mg/10mg film-coated tablets, in the treatment of type 2 diabetes mellitus.

This withdrawal is based on the major objection presented in the Qtern Rapporteur Assessment Report dated 27 March 2018 in EMEA/H/C/004057/II/0013.

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.

Yours Sincerely,



AstraZeneca AB

