



**GlaxoSmithKline Research
& Development Limited**
Stockley Park West
Uxbridge
Middlesex
UB11 1BU
United Kingdom

D2014-2200
27th March 2014

Dr Tomas Salmonson
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: The withdrawal of a Type II Variation to register an alternative indication.

Dear Dr Salmonson

I would like to inform you that Glaxo Group Limited has taken the decision to withdraw the Type II variation application for Marketing Authorisation of Votrient Tablets (EMEA/H/C/001141/II/022) which was intended to be used in the following indication:

Votrient is indicated for the maintenance treatment of women with International Federation of Gynecology and Obstetrics (FIGO) Stage II-IV ovarian, fallopian tube or primary peritoneal cancer who have not progressed after receiving first-line chemotherapy.

This decision was taken since the additional data required in order to address CHMP questions relating to the benefit/risk assessment of Votrient do not allow conclusion of a positive benefit-risk balance for this indication.

Yours sincerely,

