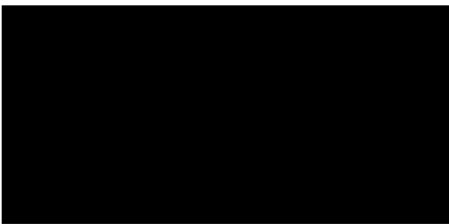



22 October 2021



Subject: Withdrawal of Type II variation for Cervarix indication extension, Human Papillomavirus vaccine (Types 16; 18), 20 µg, suspension for injection - 

Dear ,

I would like to inform you that, at this point of time, GlaxoSmithKline Biologicals SA has taken the decision to withdraw the application for a new indication for *Cervarix* vaccine, for prevention of head and neck cancers causally related to certain oncogenic Human Papillomavirus (HPV) types in males and females from the age of 9 years.

This withdrawal is based on the CHMP consideration that the submitted data, provided in support of this Type II variation, do not allow the Committee to conclude on a positive benefit-risk balance for the proposed indication.

This withdrawal does not have any impact on ongoing clinical trials with *Cervarix* vaccine. There are no consequences regarding the use of *Cervarix* for its approved indication, as the benefit-risk ratio remains positive for this registered indication.

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

GlaxoSmithKline Biologicals SA would like to sincerely thank the (Co-)Rapporteurs, EMEA, PRAC and the CHMP members for the time dedicated to reviewing this application and the support provided during the procedure.



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

Yours sincerely,

