European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Basel, 02 May 2023

To the attention of the CHMP chairman

Subject: Withdrawal of Marketing Authorisation Application for Susvimo - (PDS-EMEA/H/C/005610)

Dear Dr. Enzmann,

We would like to inform you that, at this point of time, Roche Registration GmbH has taken the decision to withdraw the application for Marketing Authorisation of the Port Delivery System with ranibizumab (PDS)/Susvimo which was intended to be used for nAMD (Reference EMEA/H/C/005610).

This withdrawal is based on the current status of the Notified Body review for the PDS devices and the CHMP requirement for providing EU declaration of conformity and EU certificates for the PDS devices with the responses to the List of Outstanding Issues.

This withdrawal does not have any impact on any ongoing clinical trials with the PDS.

Roche Registration GmbH reserves the right to make further submissions at a future date in this or other therapeutic indication(s) based on the availability of the EU declaration of conformity and EU certificates for the PDS devices.

Roche Registration GmbH would like to sincerely thank the (Co-)Rapporteurs, EMA, PRAC and CHMP members for the time dedicated to reviewing this application and the support provided during the procedure.

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

Yours sincerely,

On behalf of the Marketing Authorization Applicant, Roche Registration GmBH