

From: Polo, Stephanie
Sent: Friday, March 29, 2019 4:02 PM
To: 'Patrick.O'Neil@sanofi.com' <Patrick.O'Neil@sanofi.com>
Cc: Prutzman, Kirk C <Kirk.Prutzman@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>
Subject: STN 125682-Information Request

Dear Mr. O'Neil,

We have the following request for additional information regarding STN 125682 (Dengue Tetravalent Vaccine, Live):

We refer to your email dated March 11, 2019, in which you submitted a proposal to address the topic of enhanced pharmacovigilance that was raised during the Late-Cycle Meeting held on February 20, 2019.

1. What is the timeline for your proposed strategies to support the appropriate use of Dengvaxia according to the label? Are interim updates (e.g., within periodic safety reports/periodic safety update reports (PSURs)) planned?
2. We note that your pharmacovigilance plan for Dengvaxia includes a targeted follow-up questionnaire to be administered for reports of severe or hospitalized dengue in vaccinated individuals. Can you describe your plans for how you would learn of these cases? Do you have, or plan to have, any collaborations/networking with hospitals in Puerto Rico? Also, will the targeted follow-up questionnaire facilitate linkage of a hospitalized or severe dengue case to the individual's pre-vaccination serostatus assessment captured in the Puerto Rican Immunization Registry (PRIR)?

Please submit your proposal and address these questions in an amendment to STN 125682 by Monday, April 8, 2019.

If you have any questions about this communication, please contact Kirk Prutzman, Stephanie Polo or Ramachandra Naik at (301) 796-2640.

Best regards,

Stephanie Polo

Primary Reviewer/Regulatory Project Manager

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