

From: Polo, Stephanie
Sent: Friday, October 05, 2018 5:36 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, Attenuated]):

1. For all postmarket adverse event (AE) reports for Dengvaxia received in the Sanofi pharmacovigilance database, please provide the following:
 - a. Please fill in the tables below to provide the number of reports received by age of vaccinee and country of reporter, each stratified by seriousness.
 - b. Indicate the criteria by which the seriousness of AE reports is determined.
2. Please provide the full AE reports for all deaths, including the narrative portion and any supporting documentation.

Age of vaccinee (years)	Death (n)	Non-fatal Serious (n)	Non-serious (n)	Total (n)
<9				
≥9 to <18				
≥18 to ≤45				
>45				
Age unreported				
All ages				

Name of Country of reporter	Death (n)	Non-fatal Serious (n)	Non-serious (n)	Total (n)

Please submit your response as an amendment to STN 125682 by Friday, October 19, 2018.

We recommend that you restate each item and follow it with your explanation or clarification. Use of this format helps to organize the relevant information and provides a self-contained document that facilitates future reference. 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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