Information update on Dengvaxia

- As previously communicated, Sanofi Pasteur proposed a label update to regulatory authorities for the Dengvaxia dengue vaccine based on new analysis showing that the vaccine performance differs according to prior dengue infection status. The proposed label update suggests to include the new data findings and instructions to ensure that physicians can make appropriate vaccination decisions with their patients. Sanofi Pasteur is proposing a label update that asks healthcare professionals to assess the likelihood of prior dengue infection in an individual before vaccinating. Vaccination should only be recommended when the potential benefits outweigh the potential risks (in countries with high burden of dengue disease). For individuals who have not been previously infected by dengue virus, vaccination should not be recommended. Further updates will be provided to health care professionals, those who have been vaccinated, and anyone interested in being vaccinated against dengue in the future through communications approved by the national regulatory agencies.
- The majority of people living in high dengue endemic areas have been infected by dengue by the time they reach adolescence.[1] An estimated 75% of dengue infections could be symptomless so most people may not actually know they have had a past dengue infection.[2]
- **For people who have had a past dengue infection,** vaccination should offer strong and persistent protection against dengue hospitalizations and more severe disease.[4]
- **For those who do not know if they had a past dengue infection** before vaccination, please note that the overall results from the clinical studies performed in high dengue-endemic countries has continued to show lower rates of dengue hospitalizations and severe disease in those who have been vaccinated compared to those who have not been vaccinated.[5] Before vaccination, people should talk to their physicians to make appropriate vaccination decisions.
- **For those who did not have previous dengue infection** before vaccination, the vaccine does not cause dengue. [6]

  Furthermore severe Dengue infections are rare; it is estimated that only 1 in 800 of all dengue infections (including symptomless infections) could lead to a severe infection, [2] and the increased risk identified from the new analysis translated to 2 additional cases of “severe dengue” out of 1000 previously dengue-uninfected people vaccinated over 5 years of follow-up. Please note that the definition of “severe dengue” used in the clinical trials was a wider definition than the definition in countries that follow the WHO’s 2009 criteria, and out of the very few cases of severe Dengue in a group of around 18.000 people vaccinated in the clinical trials, all fully recovered. [5]
- As vaccination is only one of several preventive measures against Dengue, anyone who has received vaccination should still continue to take preventive actions against mosquito bites as precautionary measure. Anyone who has dengue-like symptoms and starts to experience symptoms like abdominal pain, vomiting, bleeding gums or nose, tiredness, or restlessness should seek medical attention. Early treatment and close monitoring are the key to good recovery against more severe dengue illnesses.

References

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[4] Hadinegoro SR, Arredondo-Garcia JL, Capeding MR et al. Efficacy and long-term safety of a dengue vaccine in regions of endemic disease. N Engl J Med 2015;373(13):1195-206

[5] Arredondo JL, Capeding MR, Frago C, et al. Long-Term Safety (Year 5) of the Recombinant Live-Attenuated Chimeric-Yellow Fever-Dengue Virus Tetravalent Dengue Vaccine (CYD-TDV) in Phase III Efficacy Trials. Poster 5328, presented at the 66th ASTMH Annual Meeting, 5-9 November, 2017, Baltimore, Maryland, USA

[6] Guy B, Barrere B, Malinowski C, et al. From research to phase III: preclinical, industrial and clinical development of the Sanofi Pasteur tetravalent dengue vaccine. Vaccine 2011;29(42):7229–41