**Model cover letter for the submission of a variation to a**

**WHO-prequalified vaccine**

(< FROM MANUFACTURER > LOGO)

<Date, YY/MM/DD>

**RE: <VACCINE PROPRIETARY / INVENTED NAME>**

Dear <Name of the Coordinator, WHO Prequalification Team>,

<Name of Manufacturer> hereby submits the variation(s) to a WHO-prequalified vaccine(s) and supporting documentation (if applicable) corresponding to the product summary file for < vaccine name>, in accordance with Chapter 5 of the *Guidance on Variations to a Prequalified Vaccine.*

The submission is also in compliance with the *Procedure for Assessing the Acceptability, in Principle, of Vaccines for purchase by United Nations agencies* (WHO Technical Report Series No. 978, Annex 6).

A short regulatory overview is provided, including discussions, agreements with the relevant national regulatory authority and potential date for implementation of the variations.

<Name & signature (s)>