

## **ANNEX to UNTAID EB17 Resolution 13 (MMV)**

### **Clarifications/ Issues to be addressed:**

Notwithstanding other information and clarifications that may be sought as part of the grant agreement and project plan development process, the Secretariat and/or the PRC specifically requires:

1. The identification of interested manufacturers for injectable artesunate and rectal artesunate is critical to the success of the project. Based on preliminary discussions with potential manufacturers, please describe their level of preparedness and estimated time for development, including pre-qualification.
2. Provide additional details on how the risks of failing to 1) meet project timelines and 2) achieve sustainability in the medium as well as long term, will be mitigated.
3. Provide additional information on the target countries' level of preparedness to scale-up use of injectable artesunate.
4. Provide additional information on case reports of adverse events (e.g. hemolytic anemia) following treatment with injectable artesunate, including 1) the number and nature of cases reported to date; and 2) MMV's current/planned activities to investigate potential adverse events following treatment with injectable artesunate, including appropriate pharmacovigilance as part of product scale-up and reporting of any known adverse events to the Uppsala Monitoring Centre (UMC).