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In reply please refer to: CPH56/MS/MA056-057-058V39a-2

Your reference:

Ms Valerie Faillat-Proux
Regulatory Affairs Pharmacist
Sanofi-Aventis Group
Access to Medicine
82 Avenue de Raspail
94255 Gentilly Cedex
France

16 August 2010

Dear Ms Faillat-Proux,

**WHO Prequalification of Medicines Programme
Variation to a product dossier**

Thank you for submitting the data for the assessment of the variation to your prequalified product dossier within the WHO Prequalification of Medicines Programme. A team of evaluators recently assessed the data submitted for

MA056: Artesunate/Amodiaquine (as Hydrochloride) 25mg/67.5mg tablets
MA057: Artesunate/Amodiaquine (as Hydrochloride) 50mg/135mg tablets
MA058: Artesunate/Amodiaquine (as Hydrochloride) 100mg/270mg tablets

Nature of the Variation: Extension shelf-life of FPP from 24 months to 36 months (Variation 39 of the Variation Guide).

Extension of shelf life from 24 months to 36 months is considered acceptable when stored below 30°C in the original container.

Commitment:

The applicant undertook to continue the stability testing for Artesunate/Amodiaquine (as Hydrochloride) 25mg/67.5mg tablets (batches 1001 and 1002) covering a period of 36 months. Any out of specification results will immediately be reported to WHO.


Also note that change in pre-qualified specification requires separate filing. You are therefore advised to file variation for change in acceptance limits for dihydroartemisinin in shelf-life specifications.

For further communication regarding the variations to your prequalified product dossier please use the e-mail address – **prequalassessment@who.int** – and kindly ensure that any such e-mail mentions the corresponding WHO product reference number.

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Your cooperation is appreciated.

Yours sincerely,



Dr Matthias Stahl
Head of Assessments
Prequalification of Medicines Programme
Quality Assurance and Safety: Medicines