



MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

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When replying please quote our ref No:
PPB/INS/GMP/LET/179/20-21

21st January 2021

Agio Pharmaceuticals Limited

T-82 & 82, M.I.D.C, Bhosari, Pune-411026, Maharashtra, India

RE: EXTENSION OF GMP CERTIFICATE VALIDITY

The COVID-19 pandemic has triggered national and international restrictions that have affected and prevented the conduct of on-site GMP inspection of **Agio Pharmaceuticals Limited** located at T-81.82.M.I.D.C, Bhosari, Pune-411026, Maharashtra, India.

In light of the severity of the current circumstances, the Kenya Pharmacy and Poisons Board (Kenya PPB) has extended the validity of your current GMP certificate until 31st December 2021 upon payment of GMP renewal fee. No further action is required from you.

Please note that this automatic extension does not cover any changes in the scope of the GMP certificate. It will support regulatory submissions and permit import of your products to Kenya to avoid disruptions in the availability of medicines.

Dosage Form	Category	Activity
Oral Solid dosage forms	General Products: Tablets, Hard Gelatin Capsule & Oral Powder for reconstitution	All manufacturing activities
Oral Liquids Dosage forms	General Products: Liquids, Syrups, Suspensions	All manufacturing activities
Topical Preparations	Ointments, Gel & Cream	All manufacturing activities
Sterile Preparations	Small Volume Parenterals	All manufacturing activities

Your obligation to comply with GMP is not waived by this extension. The Kenya PPB remains vigilant to ensure your medicines made available to patients in Kenya are Safe, of good quality and efficacious.

As soon circumstances permit, an on-site inspection will be conducted according to risk-based inspection planning taking into account the date of the last inspection.

Inspection of your site will be launched at any time and, in case of noncompliance, appropriate regulatory actions will be triggered.

Yours sincerely,


Dr. Shaban Sifuma,
HEAD GMP

FOR: CHIEF EXECUTIVE OFFICER.