

THE GOVERNMENT OF THE REPUBLIC OF THE UNION OF MYANMAR

MINISTRY OF HEALTH

23147

DEPARTMENT OF FOOD AND DRUG ADMINISTRATION

DRUG REGISTRATION CERTIFICATE

In accordance with Section (5) Sub-section (g) of the National Drug Law, it is hereby certified that the undermentioned pharmaceutical product has been granted registration with reference to the application made by,

Applicant's name GlaxoSmithKline Trading Services Limited

Address 12 Riverwalk, City west Business Campus, Dublin 24, Ireland

Name of product KOZENIS

Manufacturer Piramal Pharma Limited, Dhar, India

Dosage form Tablet

Presentation Blister pack of 2 tablets in a carton box

Therapeutic Category Antimalarial

Strength & Composition Each film coated tablet contains: Tafenoquine (as Succinate) 150mg

Sales Category Prescription Only Medicine

This certificate shall be valid until June, 2029 unless earlier suspended or cancelled.

No change in specifications of the product shall be made without approval of Department of Food and Drug Administration, Myanmar.

Ref: (3/2024)

Registration No 2906AA6002

Date of issue 26<sup>th</sup> June, 2024

Signature  11.9.2024

Name Professor Dr. Khin Zaw

Designation Director General