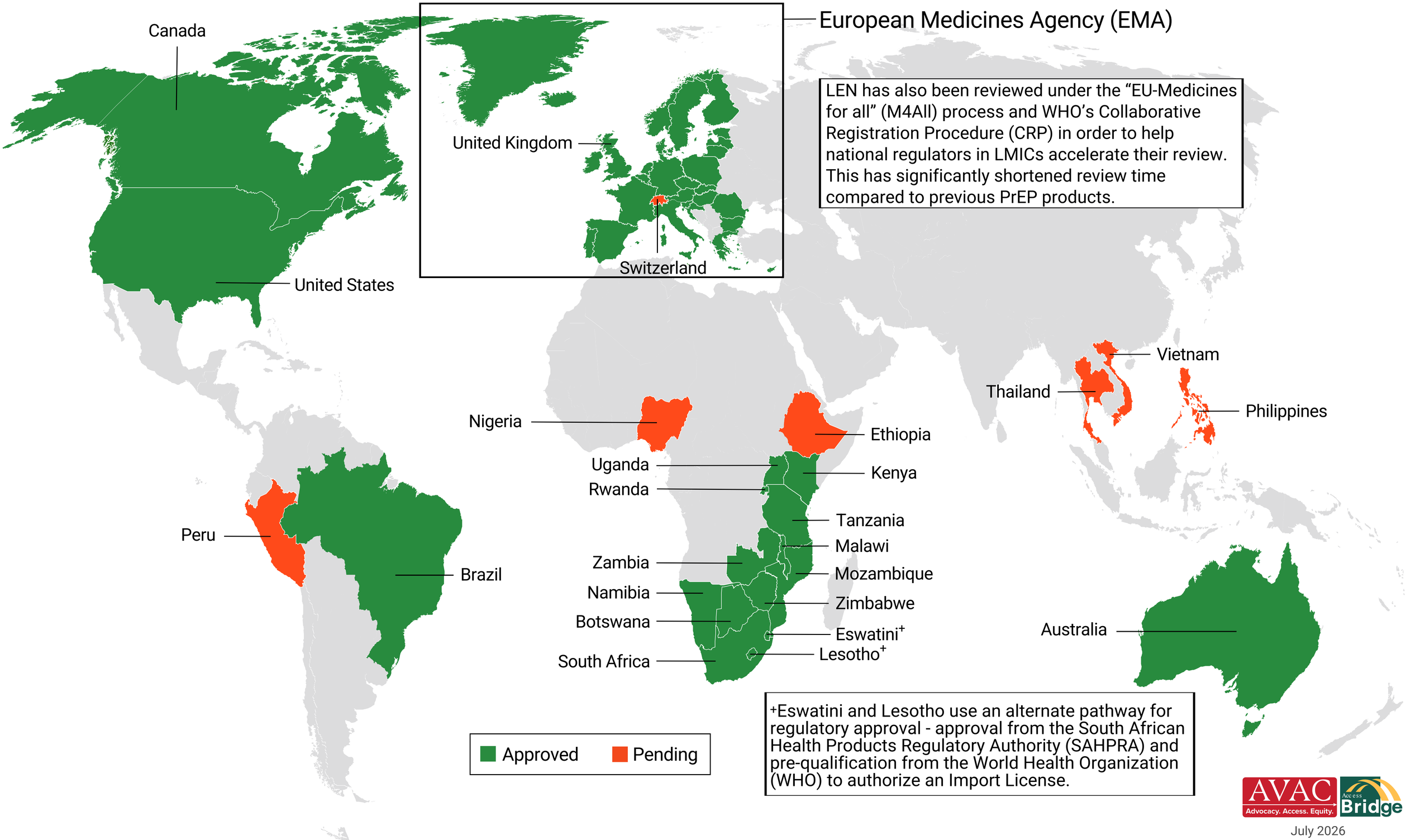
Lenacapavir Regulatory Approvals

18 approvals, 7 pending approvals as of July 2026



LEN has also been reviewed under the "EU-Medicines for all" (M4All) process and WHO's Collaborative Registration Procedure (CRP) in order to help national regulators in LMICs accelerate their review. This has significantly shortened review time compared to previous PrEP products.

+Eswatini and Lesotho use an alternate pathway for regulatory approval - approval from the South African Health Products Regulatory Authority (SAHPRA) and pre-qualification from the World Health Organization (WHO) to authorize an Import License.

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