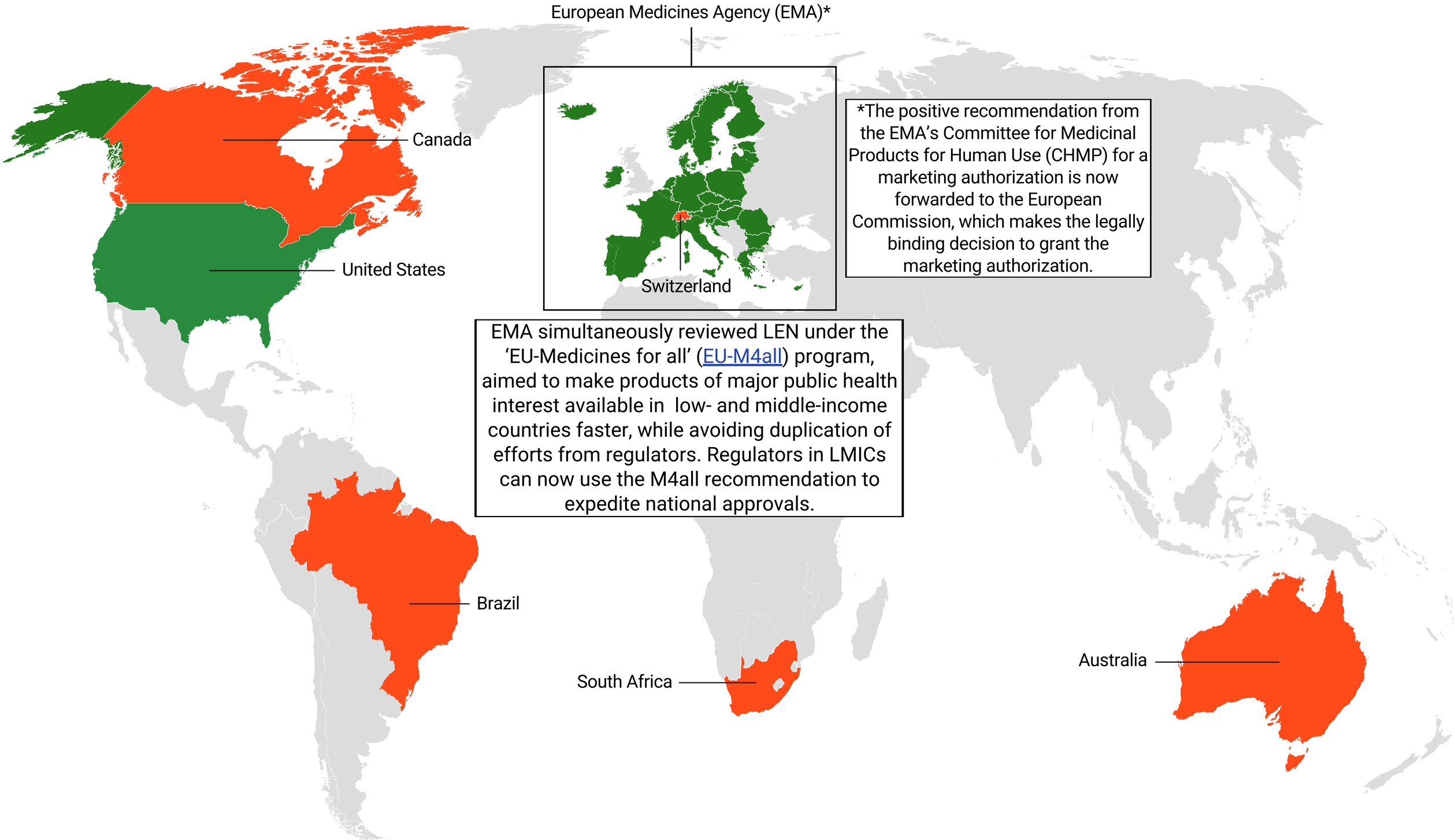
# Lenacapavir Regulatory Approval

## 2 regulatory approvals, 5 pending approvals as of July 2025




*The positive recommendation from the EMA's Committee for Medicinal Products for Human Use (CHMP) for a marketing authorization is now forwarded to the European Commission, which makes the legally binding decision to grant the marketing authorization.

EMA simultaneously reviewed LEN under the 'EU-Medicines for all' (EU-M4all) program, aimed to make products of major public health interest available in low- and middle-income countries faster, while avoiding duplication of efforts from regulators. Regulators in LMICs can now use the M4all recommendation to expedite national approvals.