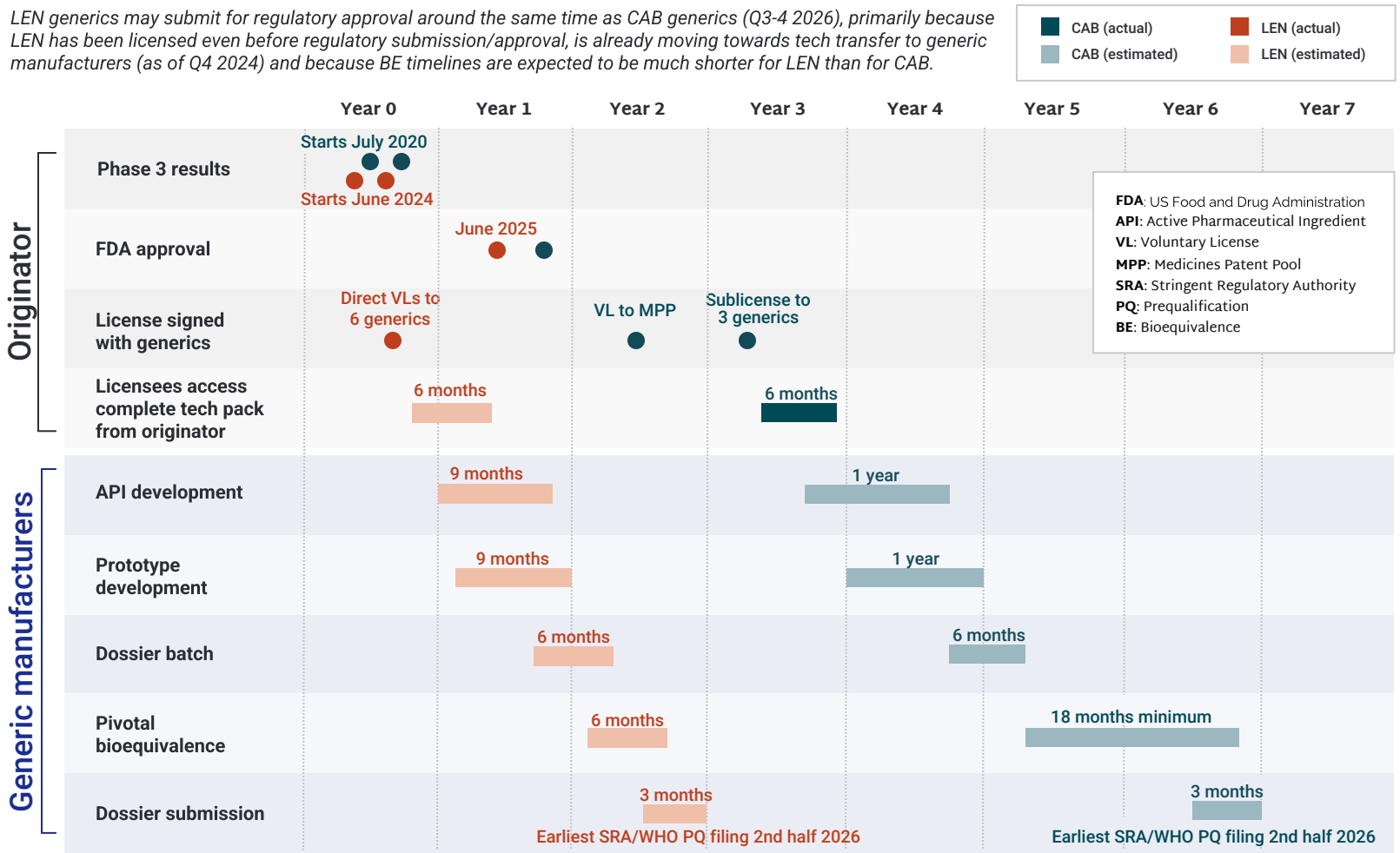
LEN generics – can we go faster?

AVAC
Advocacy. Access. Equity.

June 2025 | avac.org

LEN generics may submit for regulatory approval around the same time as CAB generics (Q3-4 2026), primarily because LEN has been licensed even before regulatory submission/approval, is already moving towards tech transfer to generic manufacturers (as of Q4 2024) and because BE timelines are expected to be much shorter for LEN than for CAB.



This graphic aims to exhibit average timelines, but it is important to acknowledge that each generic manufacturer will move at different timelines and that unanticipated delays can happen at any step of the processes shown above. This graphic therefore aims to estimate timelines but should be used as a guideline rather than taken as 100% definitive.