medicines patent pool

PRIORITISATION FRAMEWORK

CLINICAL RELEVANCE

- Safety & efficacy
- Treatment options
- Posology & method of administration
- Cross-disease impact

DISEASE BURDEN

- Prevalence & incidence
- Severity
- Epidemic risk

PATENT LANDSCAPE

- Years to patent expiry
- Geographical coverage
- Secondary patents

SERVICE DELIVERY ENABLERS

- Diagnostic requirements
- Treatment companion drugs
- Health system requirements

REGULATORY

- Regulatory pathway
- Registration of originator product in LMICs
- Regulatory cost & complexities
- Data exclusivity
- Probability of biowaiver/clinical trial waiver

MANUFACTURING

- Manufacturing simplicity
- Presentation & storage

MARKET ANALYSIS

- Affordability & availability of the candidate
- Commercial potential for generic manufacturers