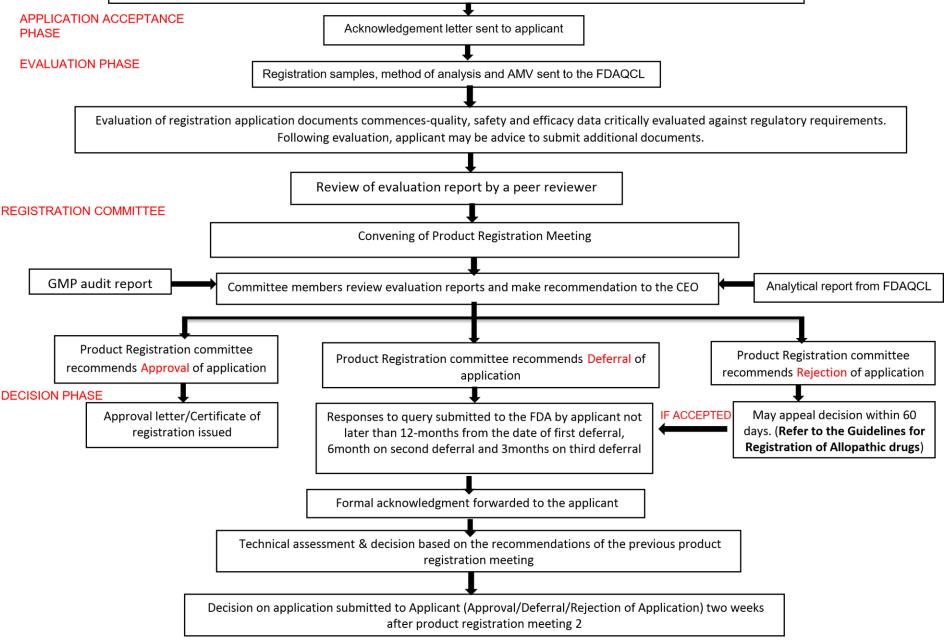


## MEDICINAL PRODUCT REGISTRATION PATHWAY AND TIMELINES

DRUG EVALUATION AND REGISTRATION DEPARTMENT(DER)

## FOOD AND DRUGS AUTHORITY (FDA)

Application received at client service. Client service perform pre-evaluation assessment. If satisfied, application fee is paid. Fees paid (base on product category). Documentation directed to the appropriate division by CEO.



## Please note

- The processing time is a clock system and stops when the FDA request for further document / clarification/ justification from the client
- 2. The counting of weeks in the chart therefore does not include time periods when applicant is expected to submit further documentation, clarification / justification to the FDA
- 3. Time for handling appeal will not be counted as part of the regular processing time.
- 4. The time between the date on letters from the FDA to the date of receipt of letters by applicant will not be counted.

## TIMELINES FOR REGISTRATION

