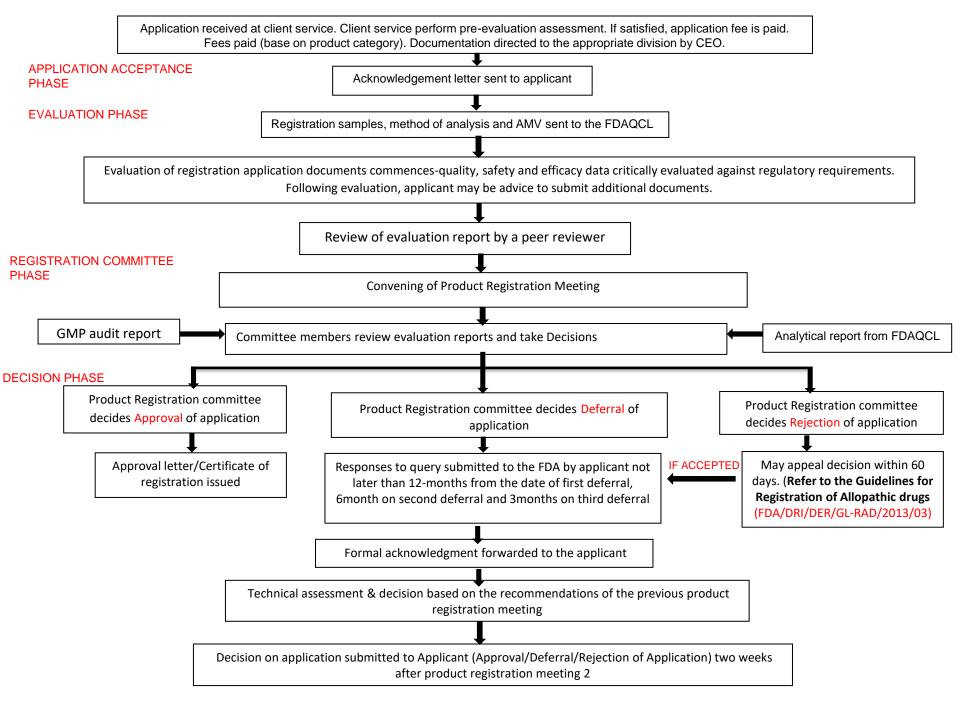


## MEDICINAL PRODUCT REGISTRATION PATHWAY AND TIMELINES

## DRUG EVALUATION AND REGISTRATION DEPARTMENT (DER) FOOD AND DRUGS AUTHORITY (FDA)



## Please note

- The processing time is a clock system and stops when the FDA request for further document / clarification/ justification from the client
- 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
- Time for handling appeal will not be counted as part of the regular processing time.
- 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

Clock Start Receipt of documentations at client service Acknowledgement of registration application 4 Weeks after Submission Evaluation of registration application and End of week sixteenth (week 10-16) Laboratory analysis of registration samples End of week twenty (week 16-20) Registration committee meeting End of week twenty two (week 20 -22) Decision on application submitted to Applicant If application is deferred, or appealed decision to a rejected application is accepted Not later than 12-months from the date of first deferral, 6 months Responses to Query submitted to the FDA on second deferral and 3 months on third deferral. End of week four from submission of queries (week 26 from initial Formal acknowledgement to the applicant submission) End of week twelve from submission of queries (week 34 from Technical assessment initial submission) End of week sixteen from submission of queries (week 38 from Decision on application submitted to Applicant initial submission)