

MEDICINAL PRODUCT RE-REGISTRATION PATHWAY AND TIMELINES

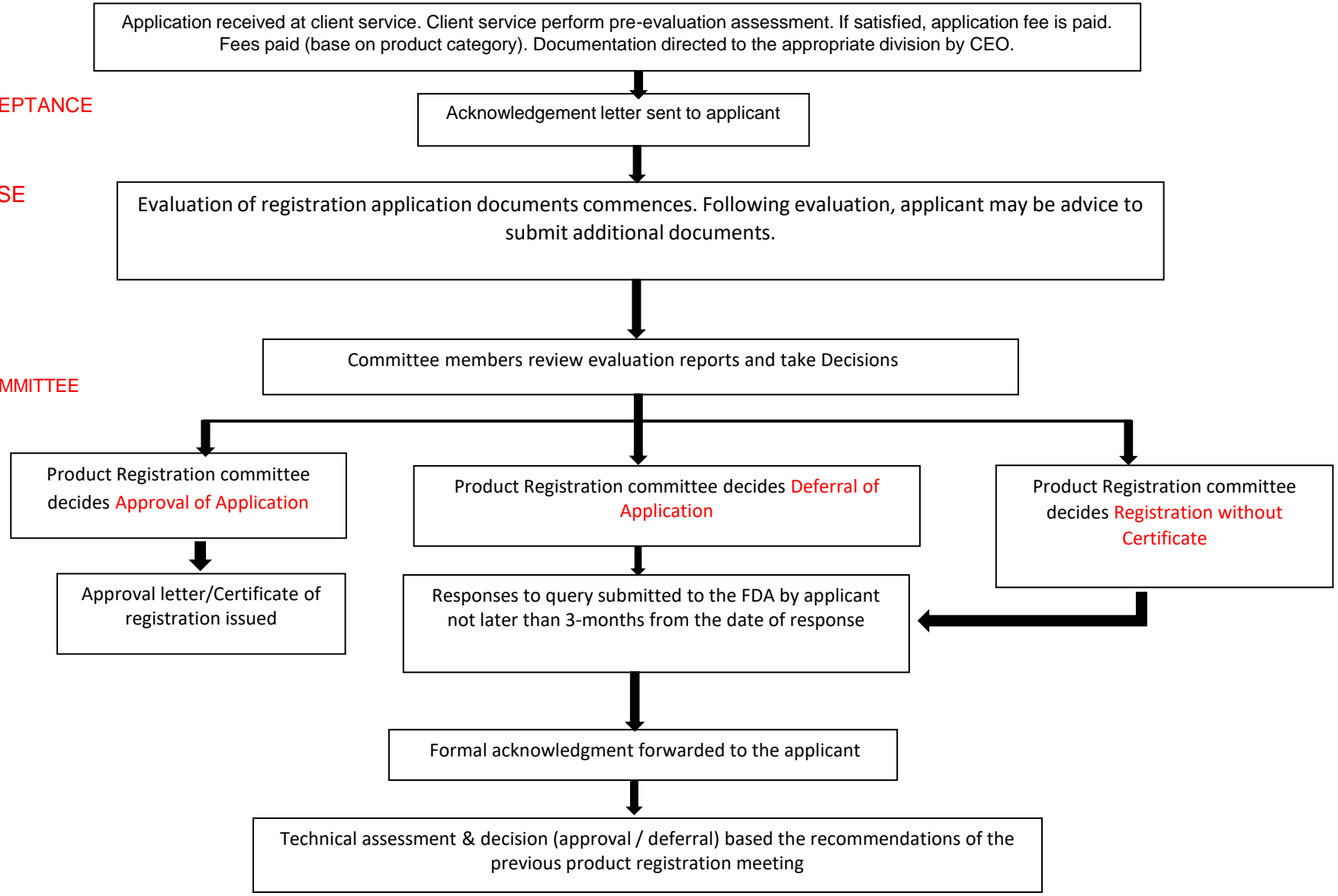
DRUG EVALUATION AND REGISTRATION DEPARTMENT
(DER)
FOOD AND DRUGS AUTHORITY
(FDA)

APPLICATION ACCEPTANCE PHASE

EVALUATION PHASE

REGISTRATION COMMITTEE PHASE

DECISION PHASE



Please note

1. 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 RE-REGISTRATION

