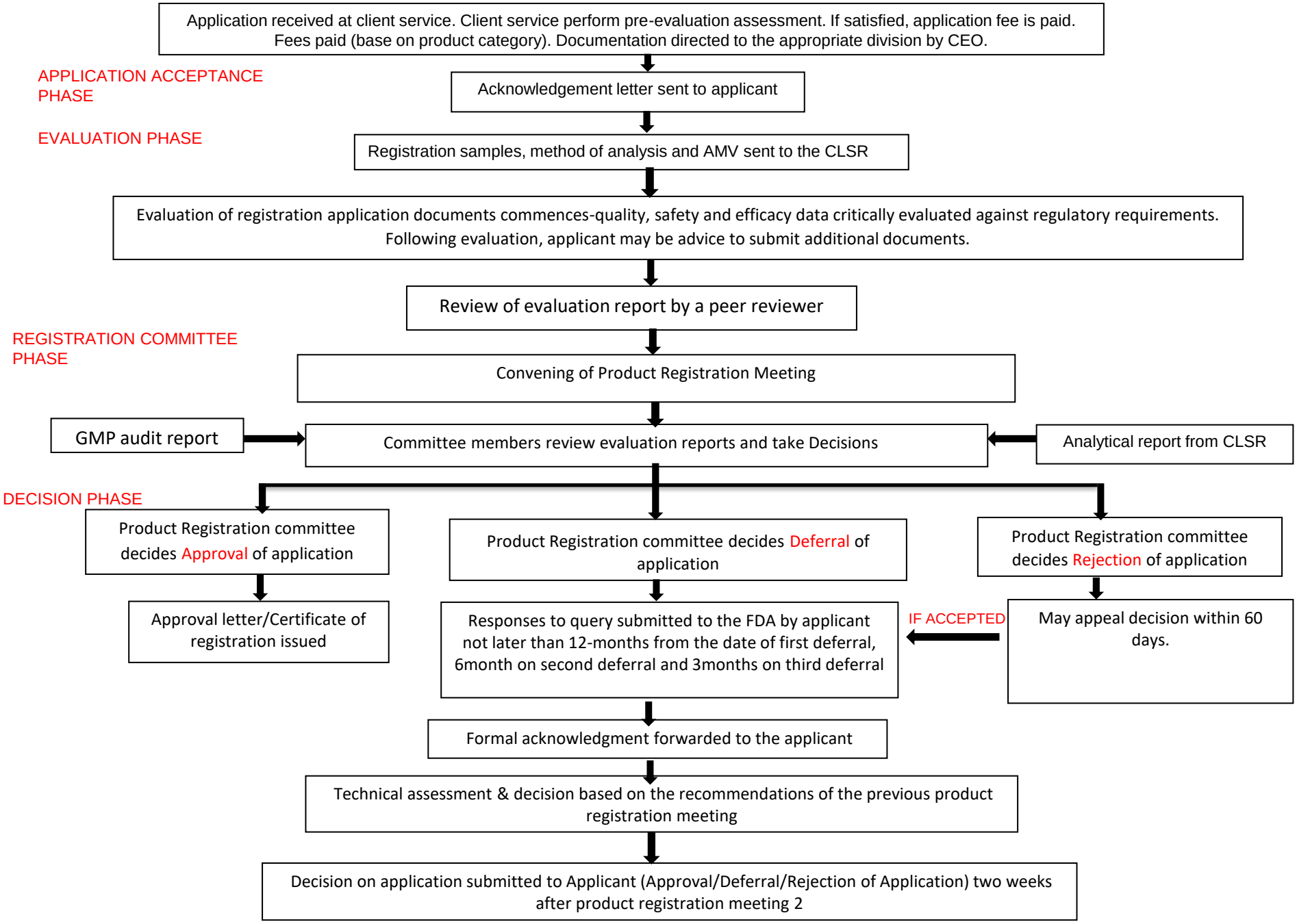
VACCINES AND BIOLOGICAL PRODUCTS DEPARTMENT

APPLICATIONS PROCESS FLOWS AND TIMELINES (WORKING DAYS)

FULL REVIEW REGISTRATION PROCESS FLOW AND TIMELINES (WORKING DAYS)


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.
APPLICATION ACCEPTANCE PHASE
Acknowledgement letter sent to applicant
EVALUATION PHASE
Registration samples, method of analysis and AMV sent to the CLSR
Evaluation of registration application documents commences-quality, safety and efficacy data critically evaluated against regulatory requirements. Following evaluation, applicant may be advice to submit additional documents.
Review of evaluation report by a peer reviewer
REGISTRATION COMMITTEE PHASE
Convening of Product Registration Meeting
GMP audit report
Committee members review evaluation reports and take Decisions
Analytical report from CLSR
DECISION PHASE
Product Registration committee decides Approval of application
Product Registration committee decides Deferral of application
Product Registration committee decides Rejection of application
Approval letter/Certificate of registration issued
Responses to query submitted to the FDA by applicant not later than 12-months from the date of first deferral, 6month on second deferral and 3months on third deferral
IF ACCEPTED
May appeal decision within 60 days.
Formal acknowledgment forwarded to the applicant
Technical assessment & decision based on the recommendations of the previous product registration meeting
Decision on application submitted to Applicant (Approval/Deferral/Rejection of Application) two weeks after product registration meeting 2

Please note

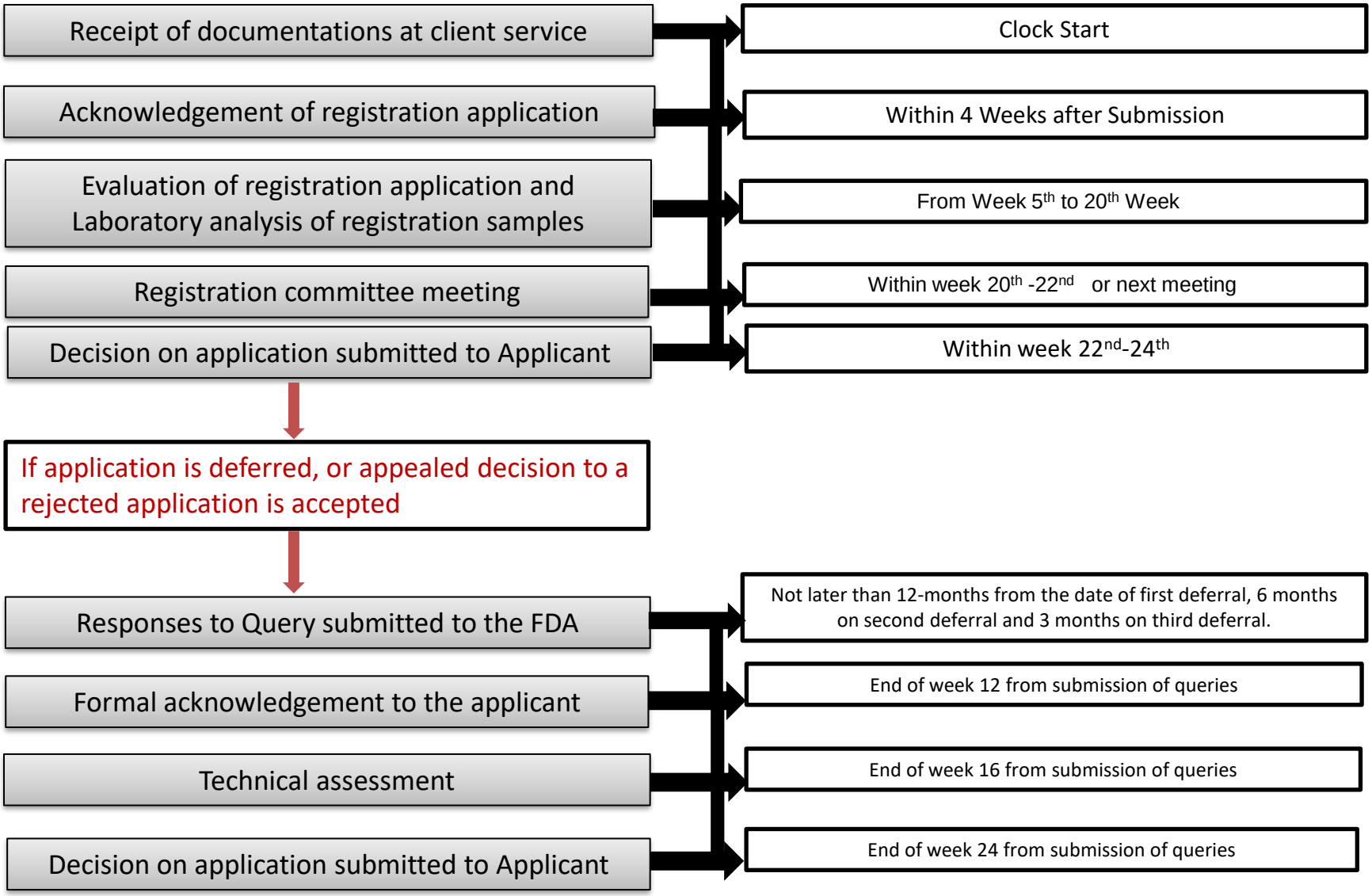
1. The processing time is a clock system and stops when the FDA request for further document / clarification/ justification from the client

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

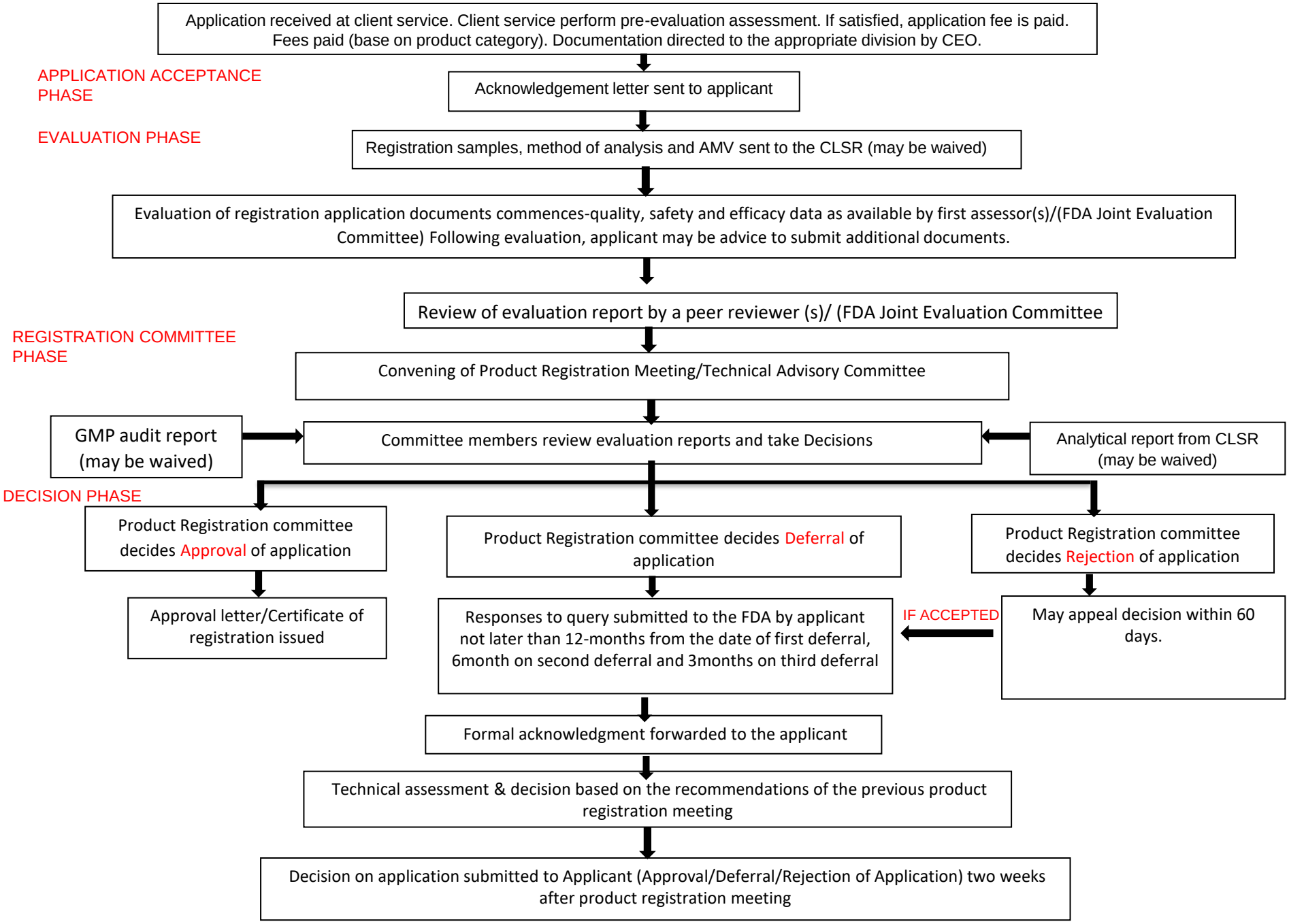
3. Time for handling appeal will not be counted as part of the regular processing time.

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 FULL REVIEW REGISTRATION



EMERGENCY USE AUTHORIZATION (EUA) PROCESS FLOW AND TIMELINES (WORKING DAYS)


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.
APPLICATION ACCEPTANCE PHASE
Acknowledgement letter sent to applicant
EVALUATION PHASE
Registration samples, method of analysis and AMV sent to the CLSR (may be waived)
Evaluation of registration application documents commences-quality, safety and efficacy data as available by first assessor(s)/(FDA Joint Evaluation Committee) Following evaluation, applicant may be advice to submit additional documents.
Review of evaluation report by a peer reviewer (s)/ (FDA Joint Evaluation Committee
REGISTRATION COMMITTEE PHASE
Convening of Product Registration Meeting/Technical Advisory Committee
GMP audit report (may be waived)
Committee members review evaluation reports and take Decisions
Analytical report from CLSR (may be waived)
DECISION PHASE
Product Registration committee decides Approval of application
Product Registration committee decides Deferral of application
Product Registration committee decides Rejection of application
Approval letter/Certificate of registration issued
Responses to query submitted to the FDA by applicant not later than 12-months from the date of first deferral, 6month on second deferral and 3months on third deferral
IF ACCEPTED
May appeal decision within 60 days.
Formal acknowledgment forwarded to the applicant
Technical assessment & decision based on the recommendations of the previous product registration meeting
Decision on application submitted to Applicant (Approval/Deferral/Rejection of Application) two weeks after product registration meeting

Please note

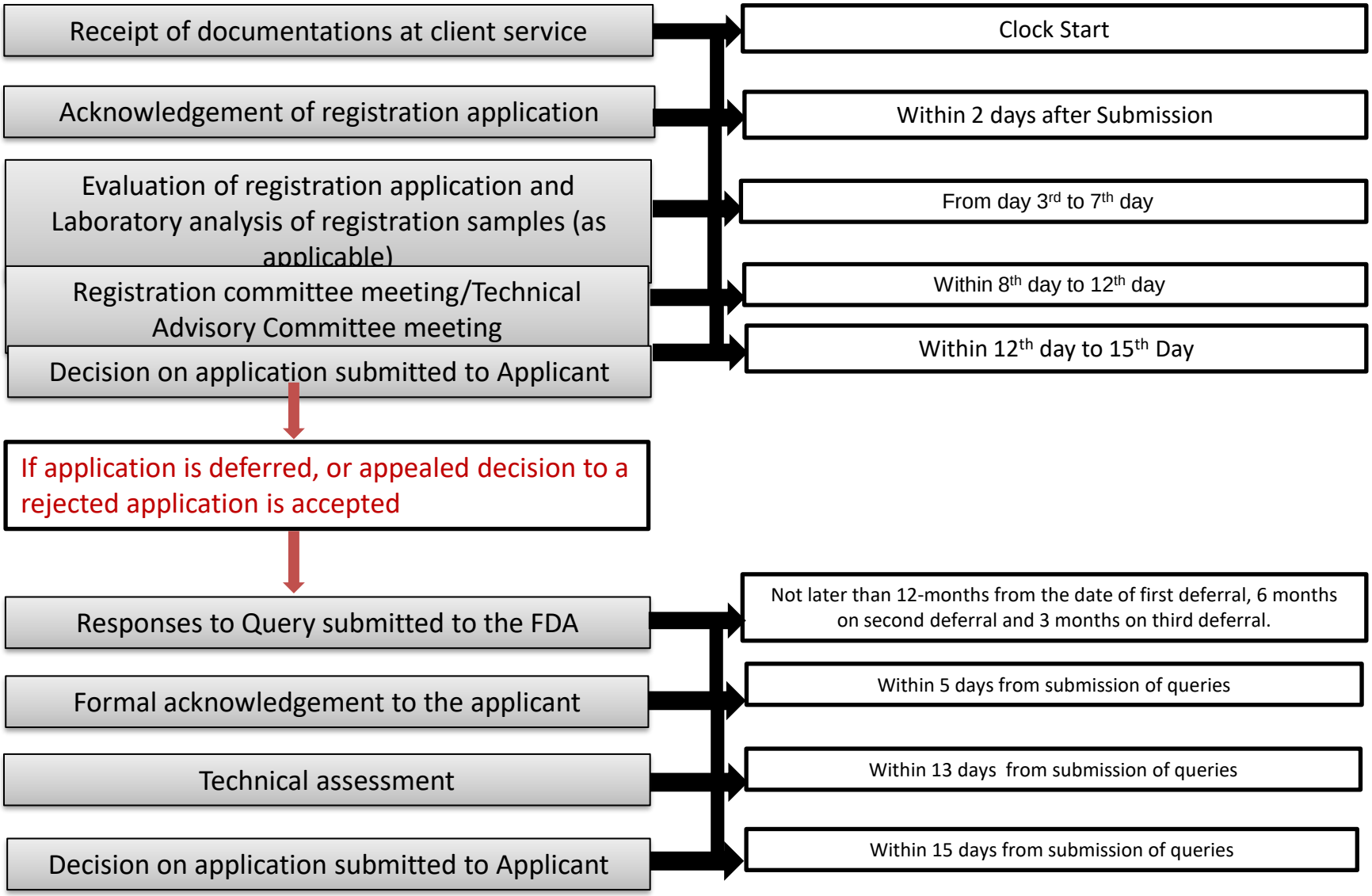
1. The processing time is a clock system and stops when the FDA request for further document / clarification/ justification from the client

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.

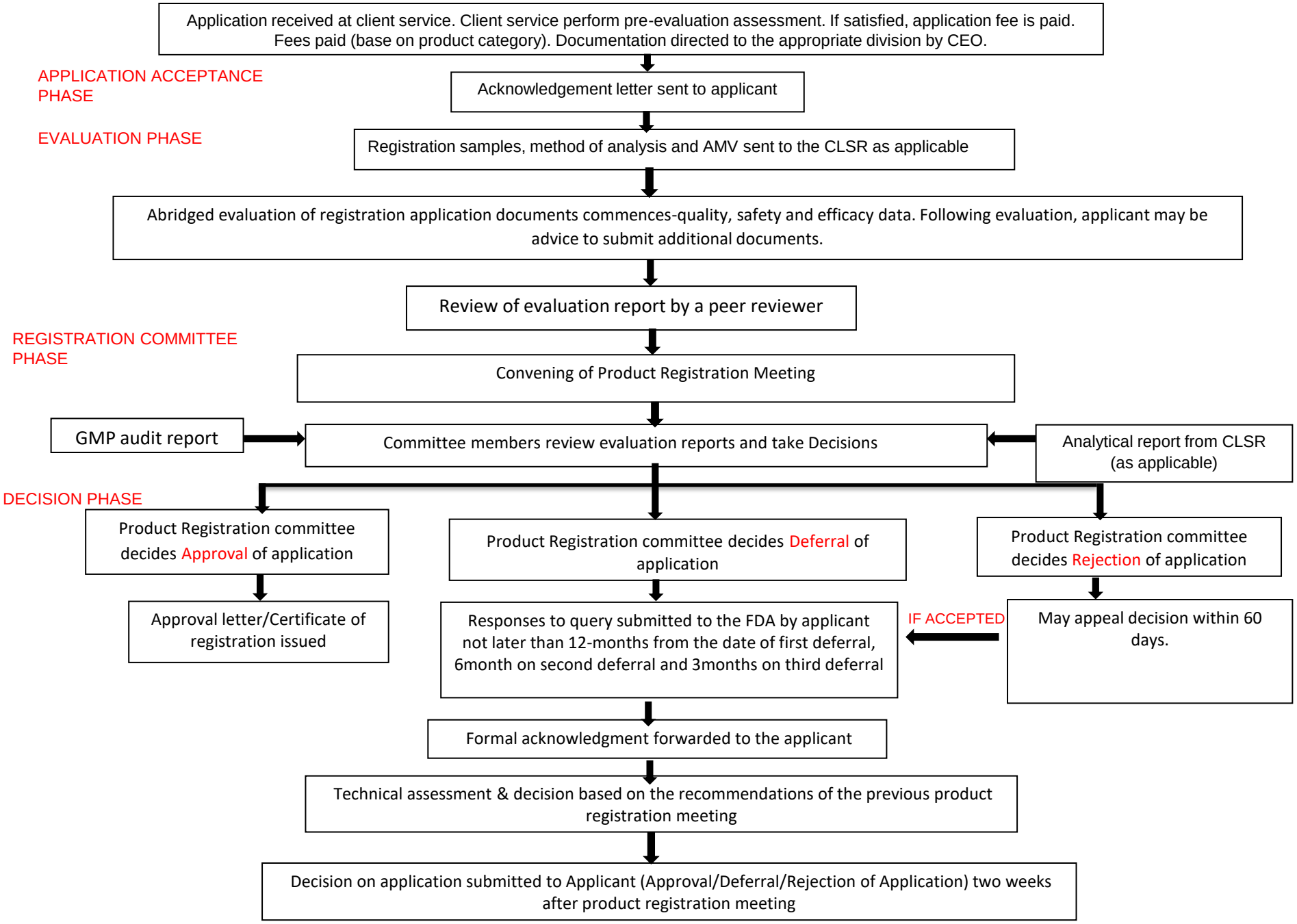
4. The time between the date on letters from the FDA to the date of receipt of letters by applicant will not be counted.

TIMELINES FOR EUA



RELIANCE REGISTRATION PROCESS FLOW AND TIMELINES (WORKING DAYS)

Generated by: Vaccines and Biological Product Department


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.
APPLICATION ACCEPTANCE PHASE
Acknowledgement letter sent to applicant
EVALUATION PHASE
Registration samples, method of analysis and AMV sent to the CLSR as applicable
Abridged evaluation of registration application documents commences-quality, safety and efficacy data. Following evaluation, applicant may be advice to submit additional documents.
Review of evaluation report by a peer reviewer
REGISTRATION COMMITTEE PHASE
Convening of Product Registration Meeting
GMP audit report
Committee members review evaluation reports and take Decisions
Analytical report from CLSR (as applicable)
DECISION PHASE
Product Registration committee decides Approval of application
Product Registration committee decides Deferral of application
Product Registration committee decides Rejection of application
Approval letter/Certificate of registration issued
Responses to query submitted to the FDA by applicant not later than 12-months from the date of first deferral, 6month on second deferral and 3months on third deferral
IF ACCEPTED
May appeal decision within 60 days.
Formal acknowledgment forwarded to the applicant
Technical assessment & decision based on the recommendations of the previous product registration meeting
Decision on application submitted to Applicant (Approval/Deferral/Rejection of Application) two weeks after product registration meeting

Please note

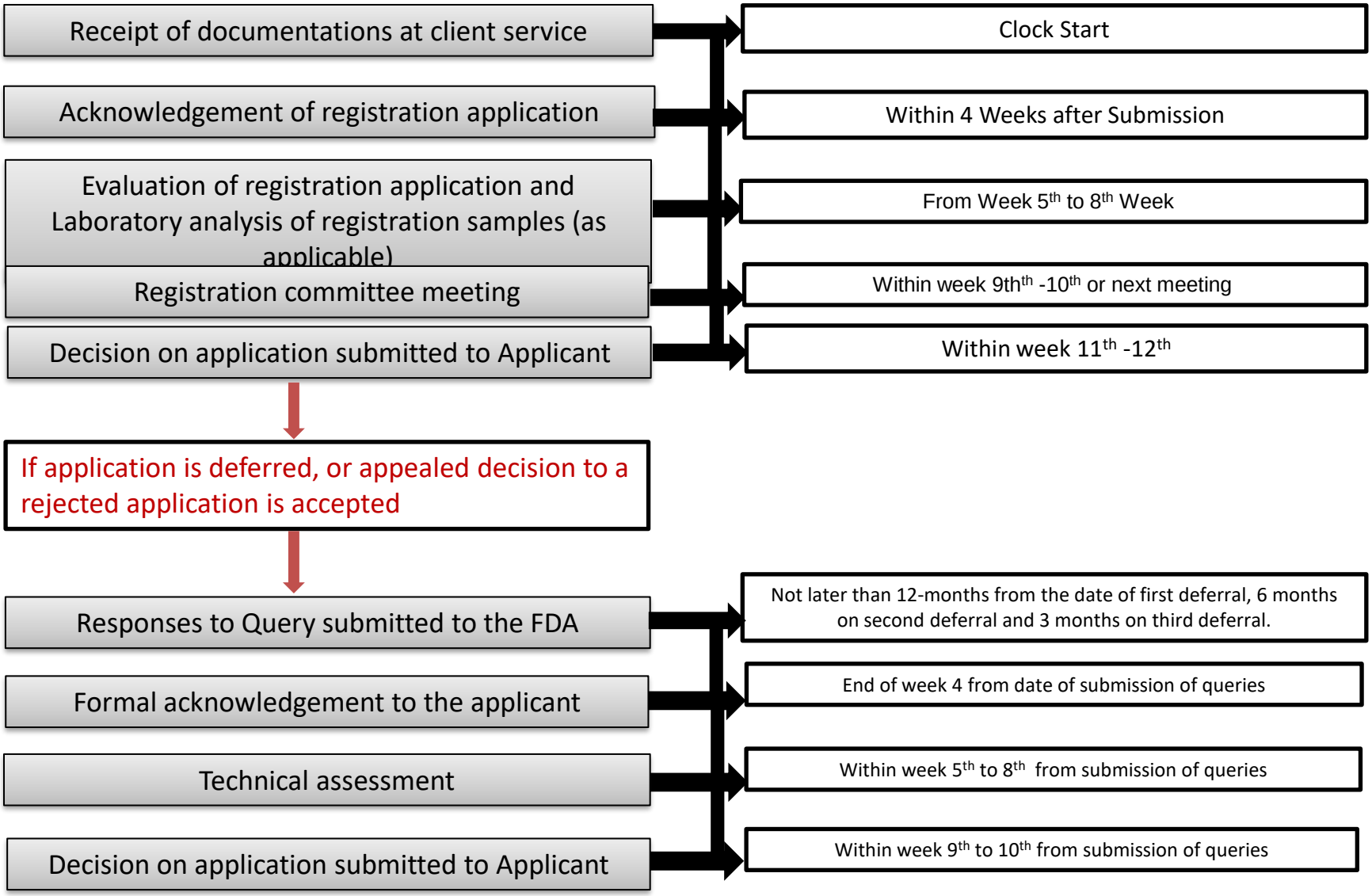
1. The processing time is a clock system and stops when the FDA request for further document / clarification/ justification from the client

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.

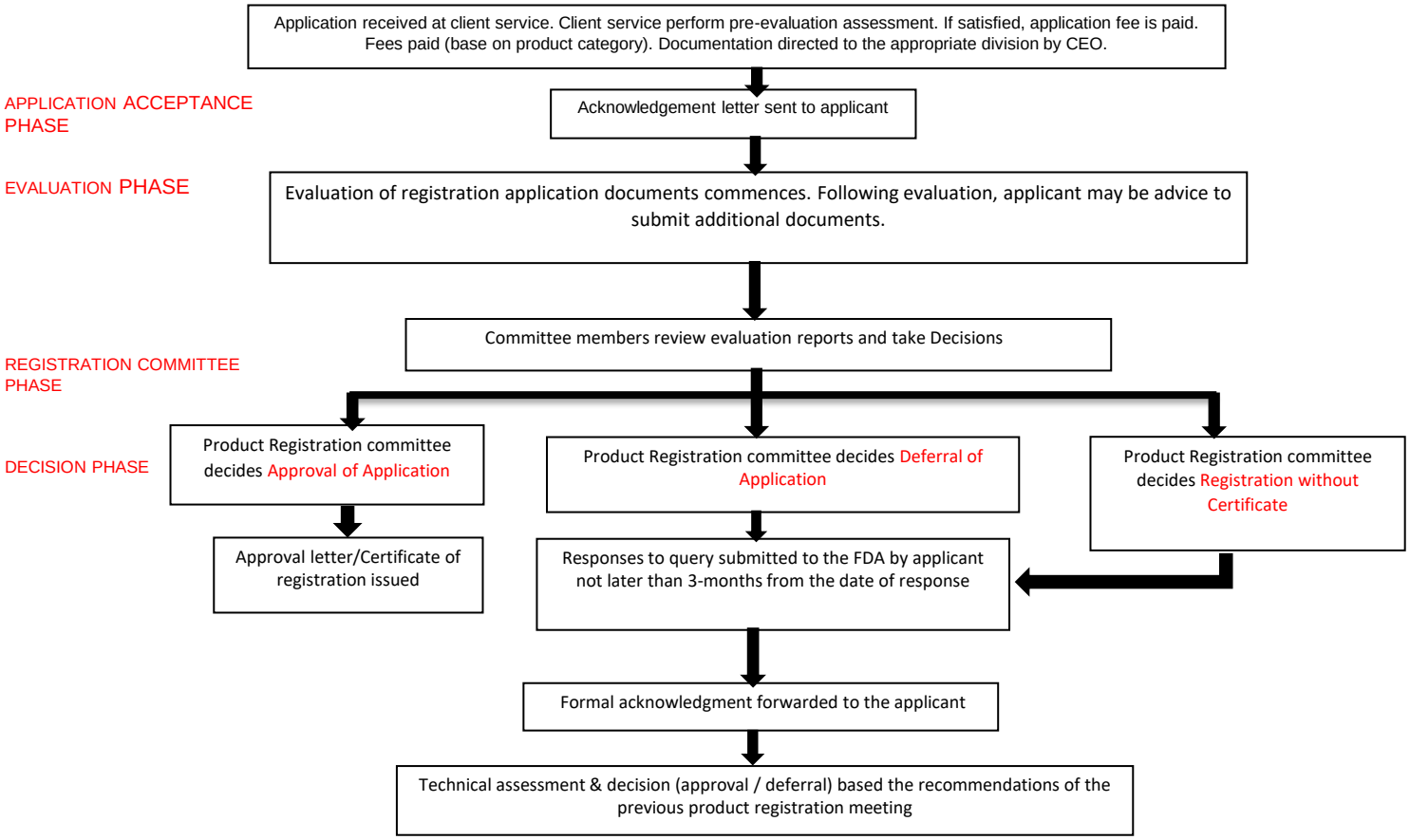
4. The time between the date on letters from the FDA to the date of receipt of letters by applicant will not be counted.

TIMELINES FOR RELIANCE PATHWAY



REGISTRATION RENEWAL PROCESS FLOW AND TIMELINES (WORKING DAYS)

Generated by: Vaccines and Biological Products Department



Please note

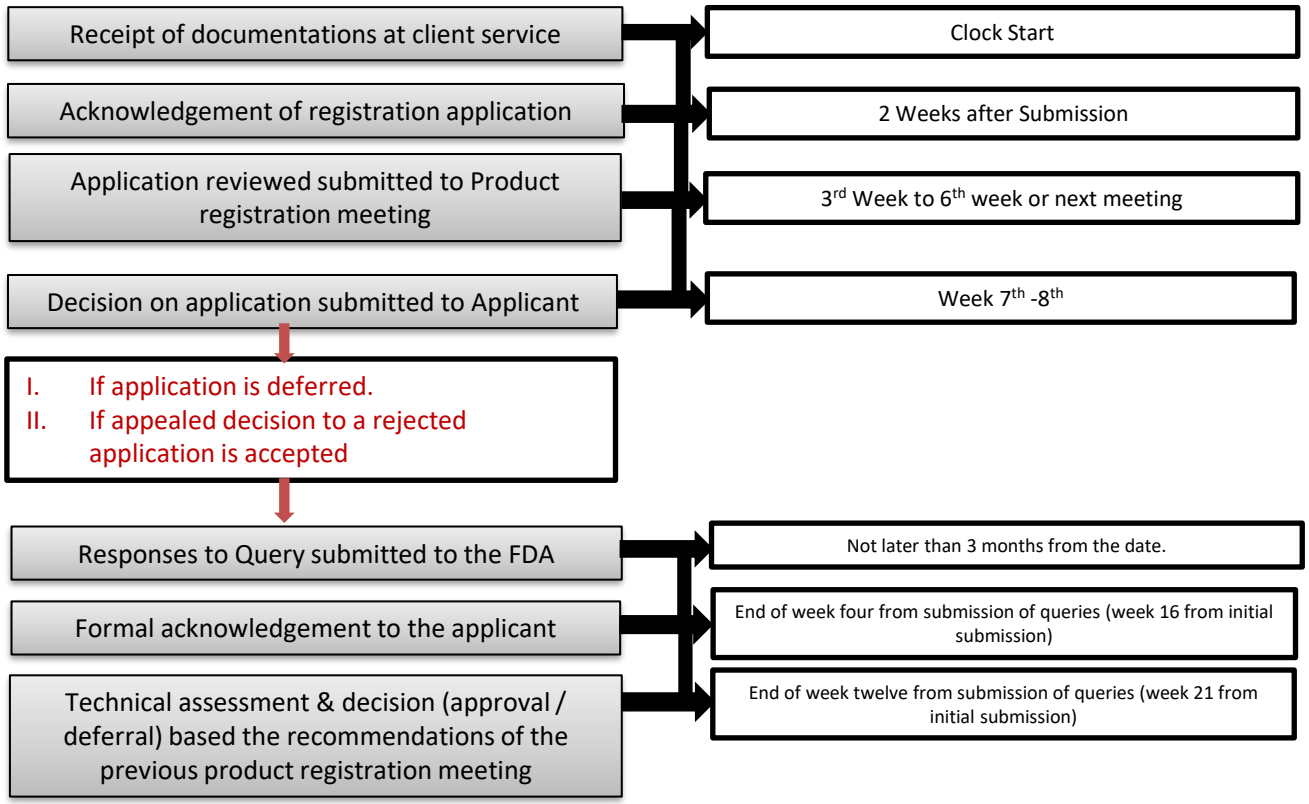
1. The processing time is a clock system and stops when the FDA request for further document / clarification/ justification from the client.

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.

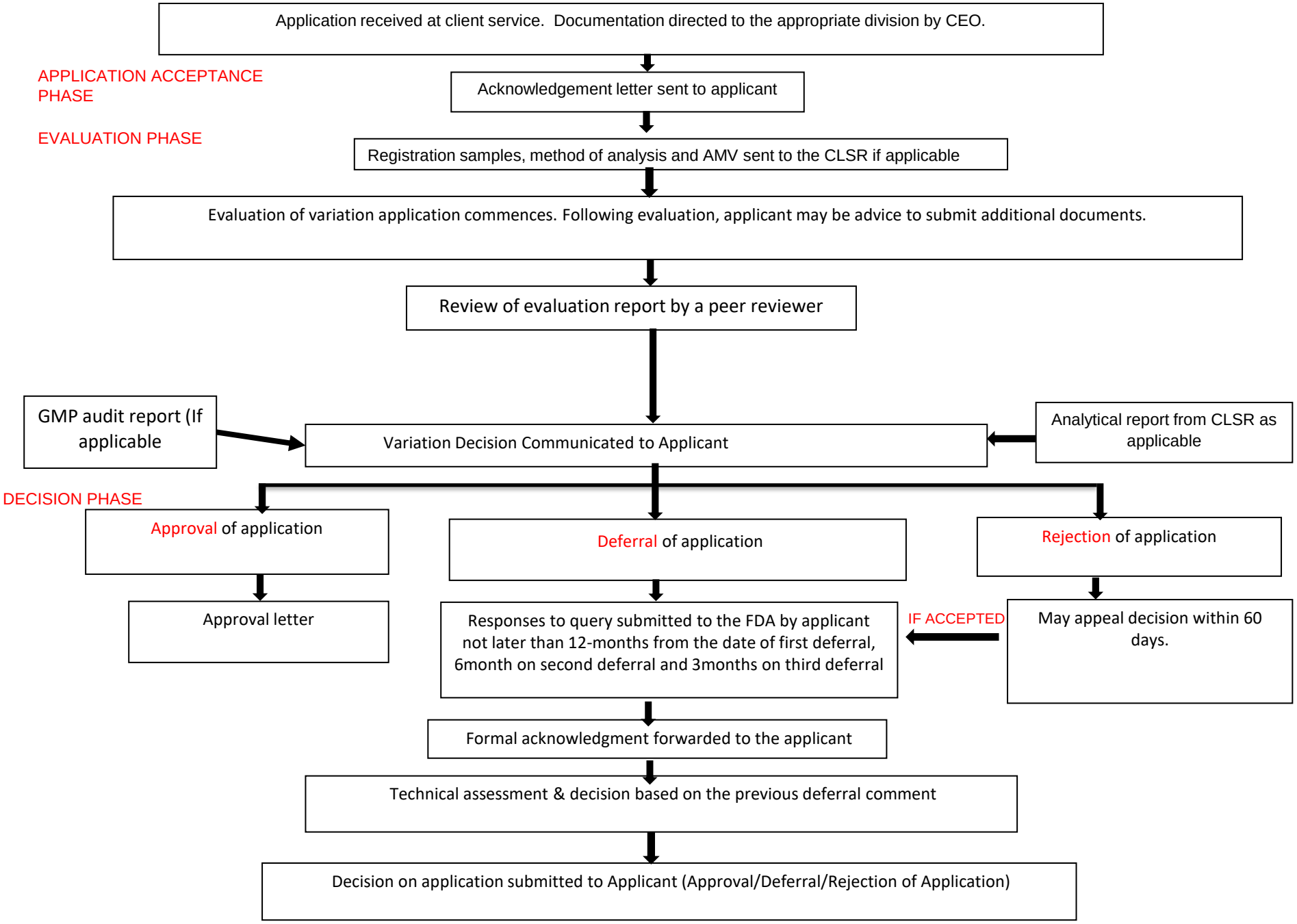
4. The time between the date on letters from the FDA to the date of receipt of letters by applicant will not be counted.

TIMELINES FOR RENEWAL OF REGISTRATION



VARIATIONS PROCESS FLOW AND TIMELINES (WORKING DAYS)

Generated by: Vaccines and Biological Product Department


Application received at client service. Documentation directed to the appropriate division by CEO.
APPLICATION ACCEPTANCE PHASE
Acknowledgement letter sent to applicant
EVALUATION PHASE
Registration samples, method of analysis and AMV sent to the CLSR if applicable
Evaluation of variation application commences. Following evaluation, applicant may be advice to submit additional documents.
Review of evaluation report by a peer reviewer
GMP audit report (If applicable
Variation Decision Communicated to Applicant
Analytical report from CLSR as applicable
DECISION PHASE
Approval of application
Deferral of application
Rejection of application
Approval letter
Responses to query submitted to the FDA by applicant not later than 12-months from the date of first deferral, 6month on second deferral and 3months on third deferral
IF ACCEPTED
May appeal decision within 60 days.
Formal acknowledgment forwarded to the applicant
Technical assessment & decision based on the previous deferral comment
Decision on application submitted to Applicant (Approval/Deferral/Rejection of Application)

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 VARIATION