Notice to applicant

Flowcharts for Ministerial Decrees 425 for the year 2015 645 for the year 2018 820 for the year 2016 Emergency Use Approval

Year 2022

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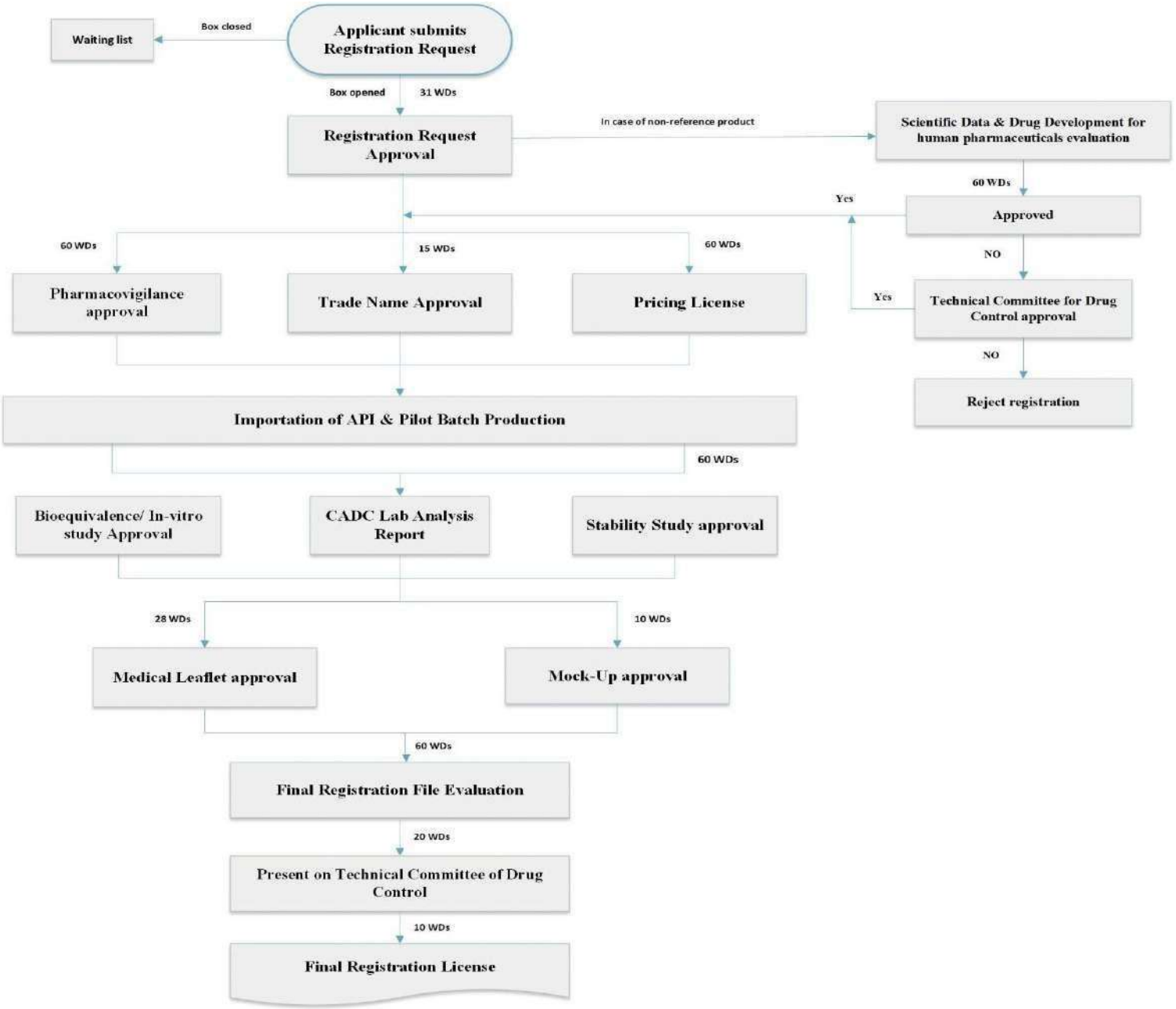
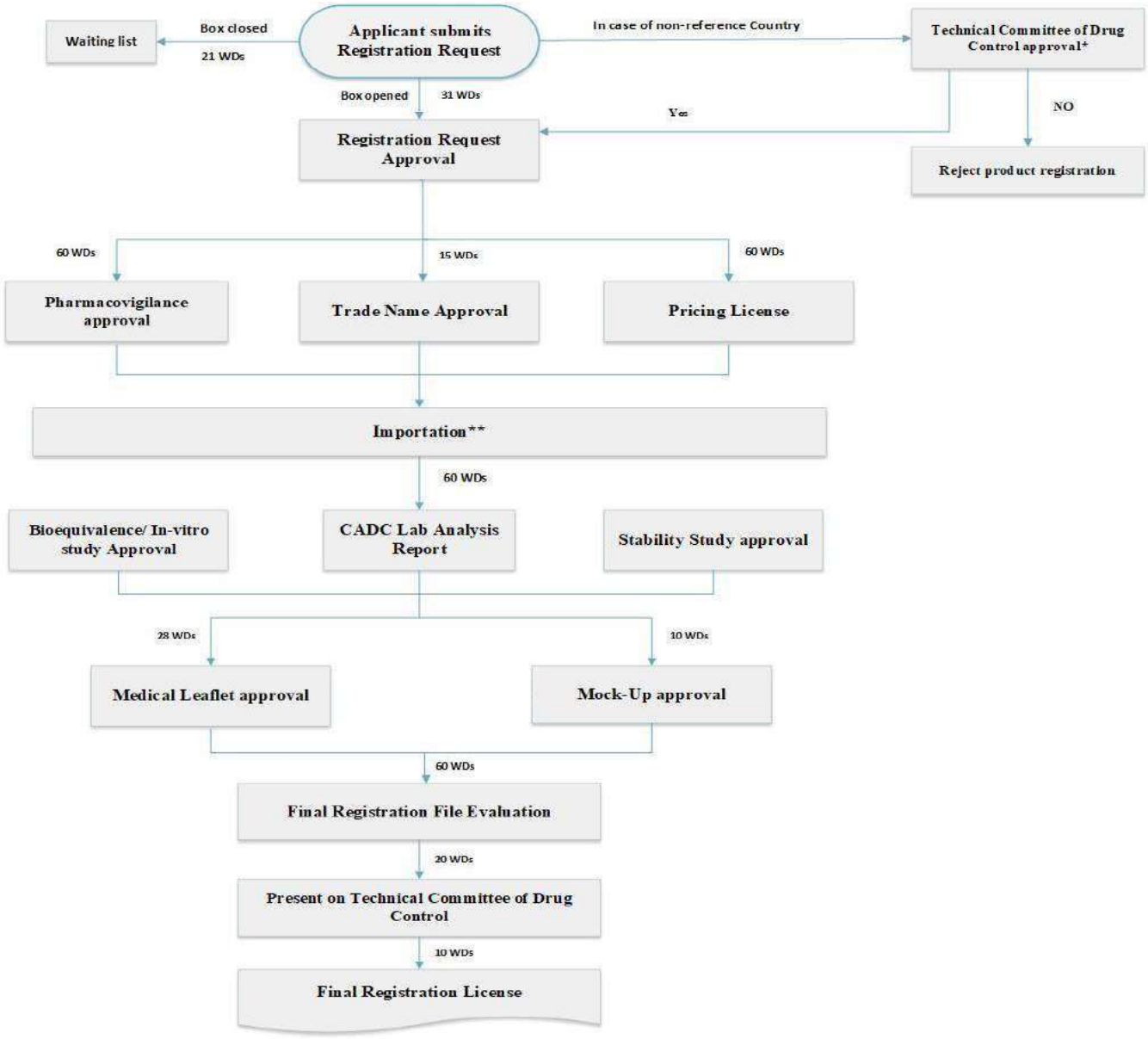
Ministerial Decree 425/2015 Flowchart for Local manufactured products with assessment timeline



- Applicant shall submit applications to each relevant division as shown at the flowchart.
- Assessment timelines start from receiving complete files from applicants.
- Applicant has the right to produce the pilot batch & submit the final registration file within 33 months from the date of Pharmacovigilance approval or Pricing approval whichever is the latest.

Ministerial Decree 425/2015 Flowchart for Imported manufactured products with assessment timelines

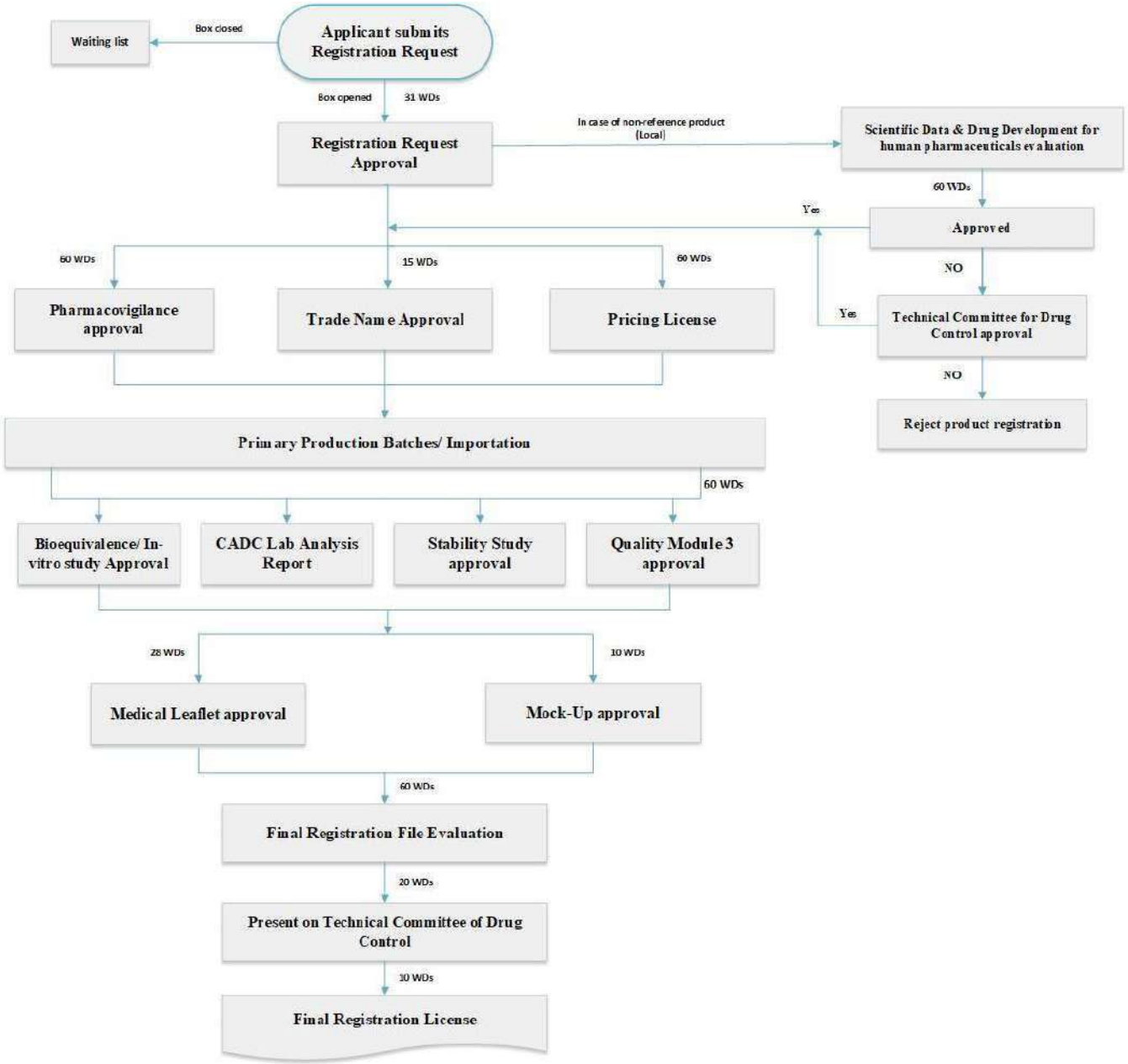


*Technical Committee for Drugs Control may transfer the request to be evaluated by the Scientific Data & Drug Development for human pharmaceuticals division and/or the Central administration of Operations

** In case of importation from reference country or from non-reference country but marketed in reference country, applicant has the right to import and analyze the product after issuing MA.

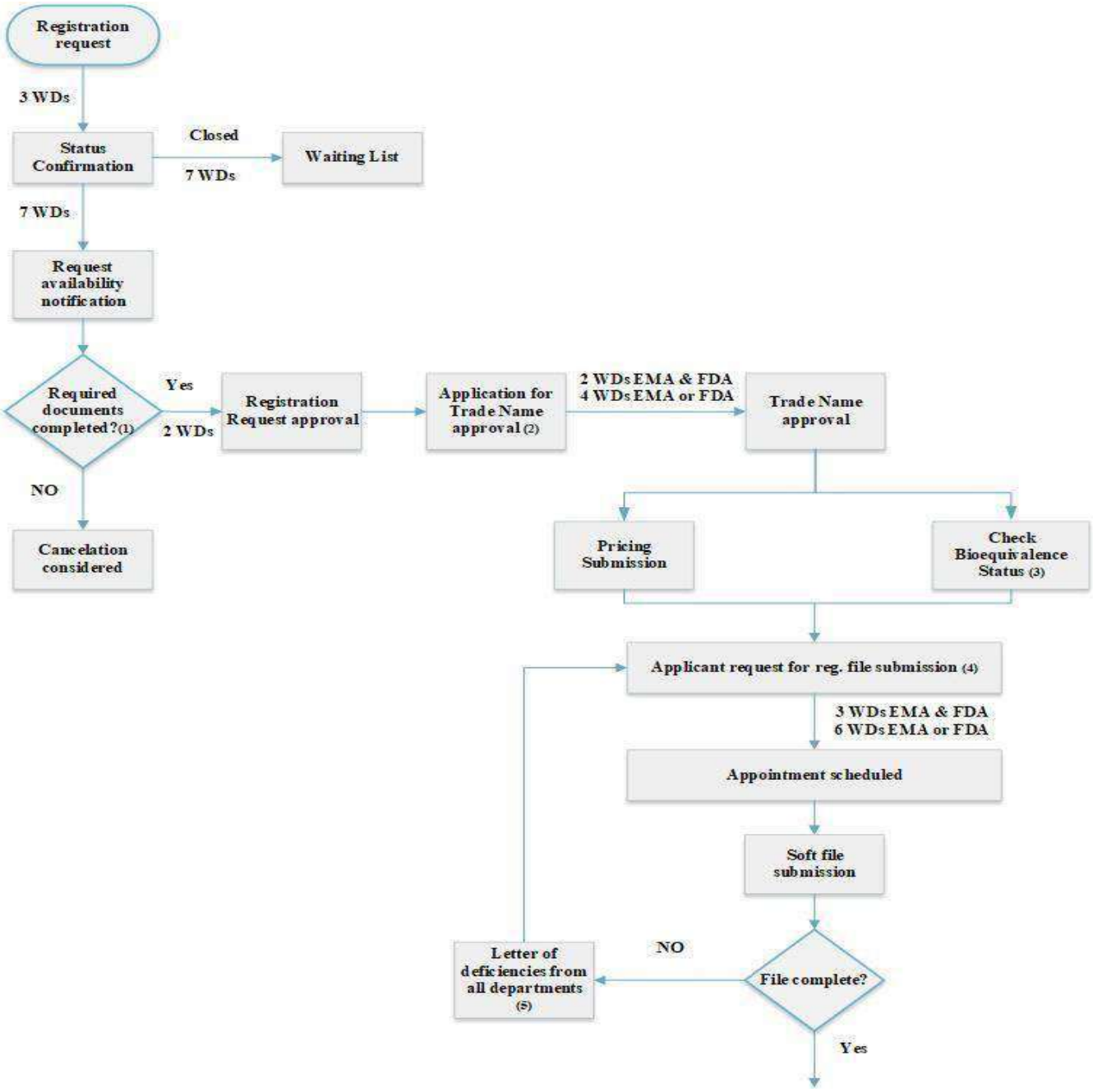
- Assessment timelines start from receiving complete files from applicants.
- Applicant shall submit applications to each relevant division as shown at the flowchart.
- Applicant has the right for importation & submission of the final registration file within 6 months from the date of Pharmacovigilance approval or Pricing approval whichever is the latest.

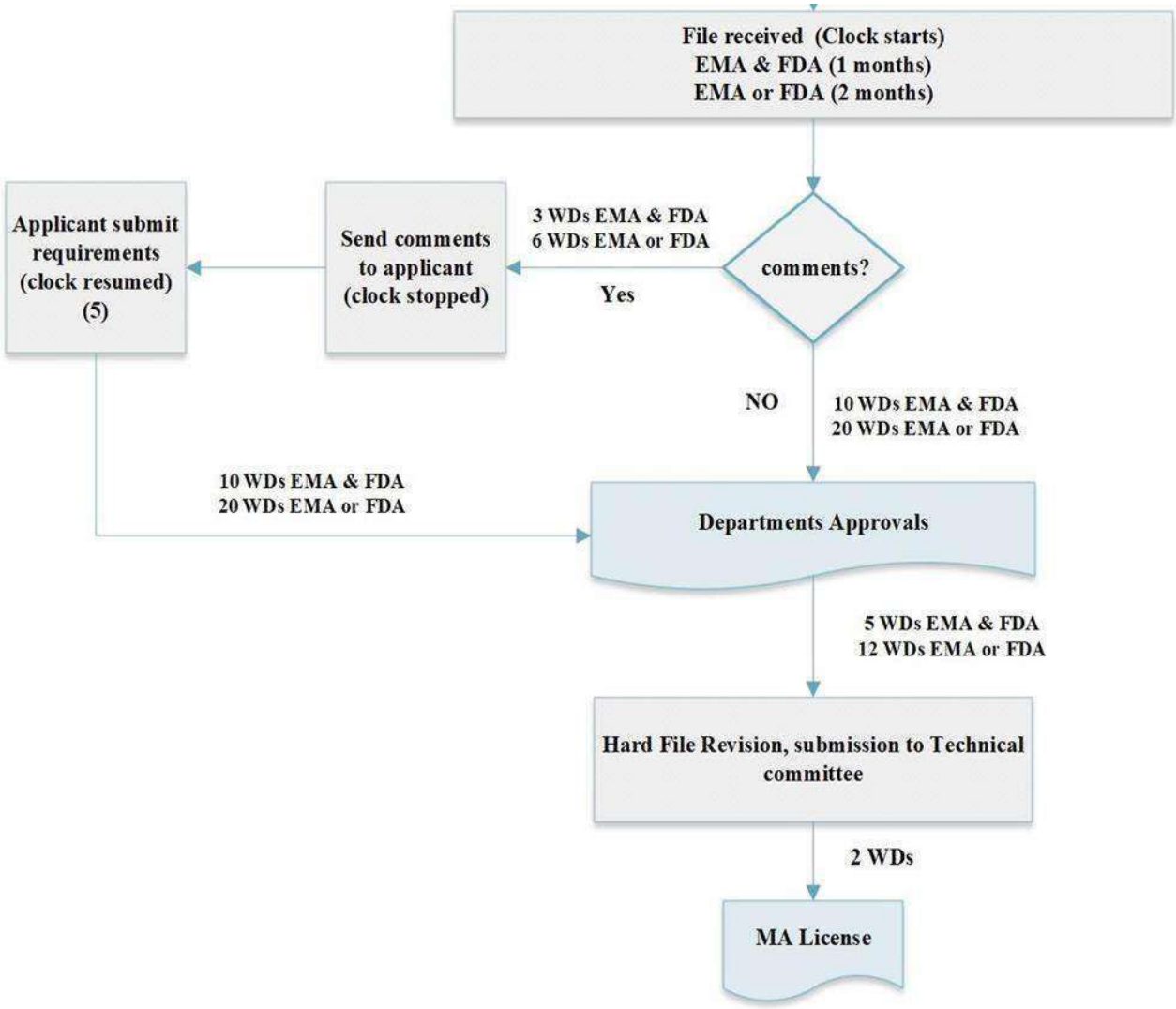
Ministerial Decree 645/2018 Flowchart for Local & Imported products with assessment timelines



- Applicant shall submit applications to each relevant division as shown at the flowchart.
- Assessment timelines start from receiving complete files from applicants.
- Grace Periods for Applicants to submit the final registration file are as follow:
  - Case One - Local: within 21 months from Pharmacovigilance approval or Pricing approval whichever is the latest.
  - Case One - Imported: within 6 months from Registration request approval.
  - Case 2, 3, 4 & 5 - within 33 months from Pharmacovigilance approval or Pricing approval whichever is the latest.

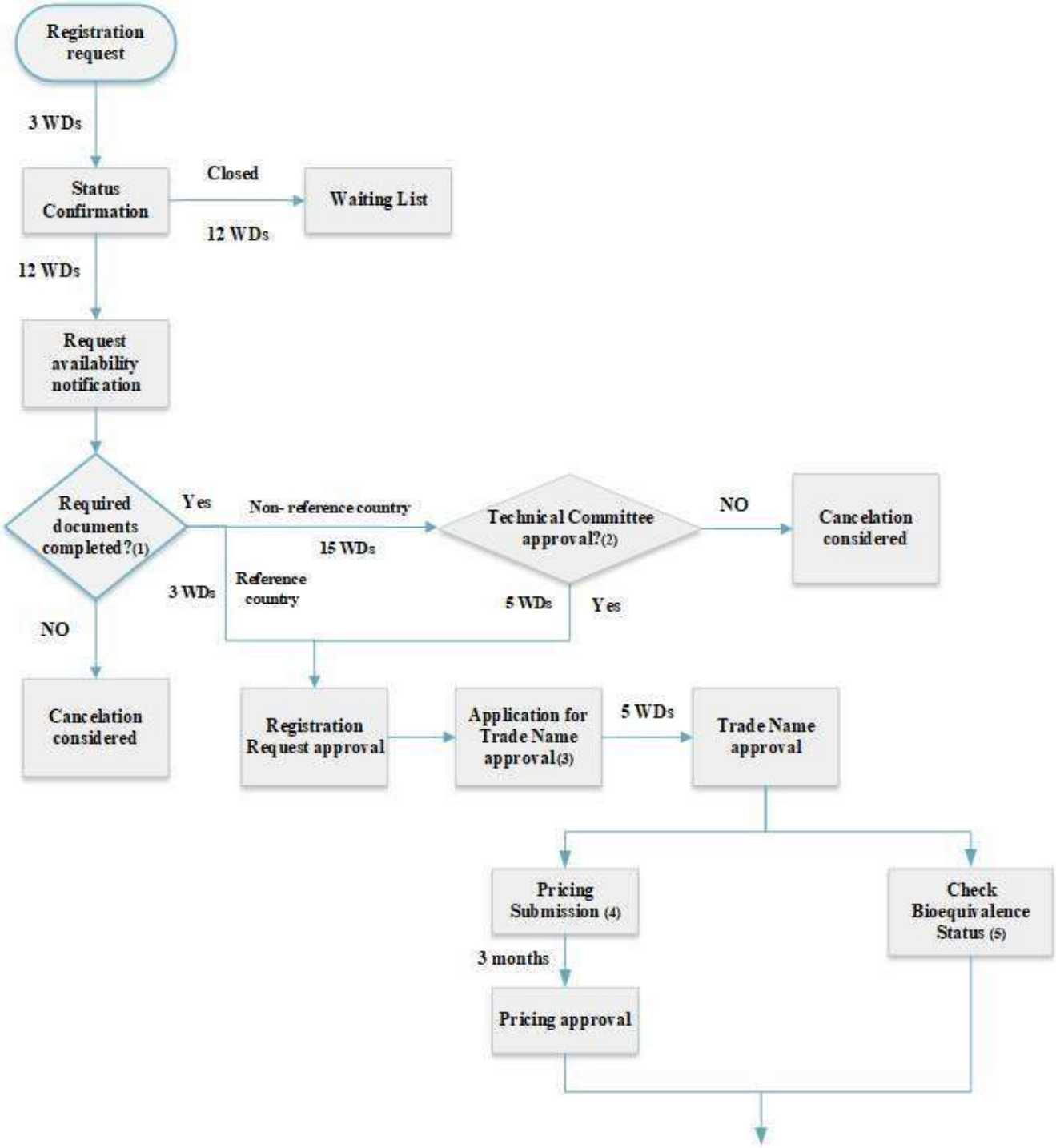
Ministerial Decree 820/2016 – EMA and/or FDA approved drugs Flowchart with assessment timelines

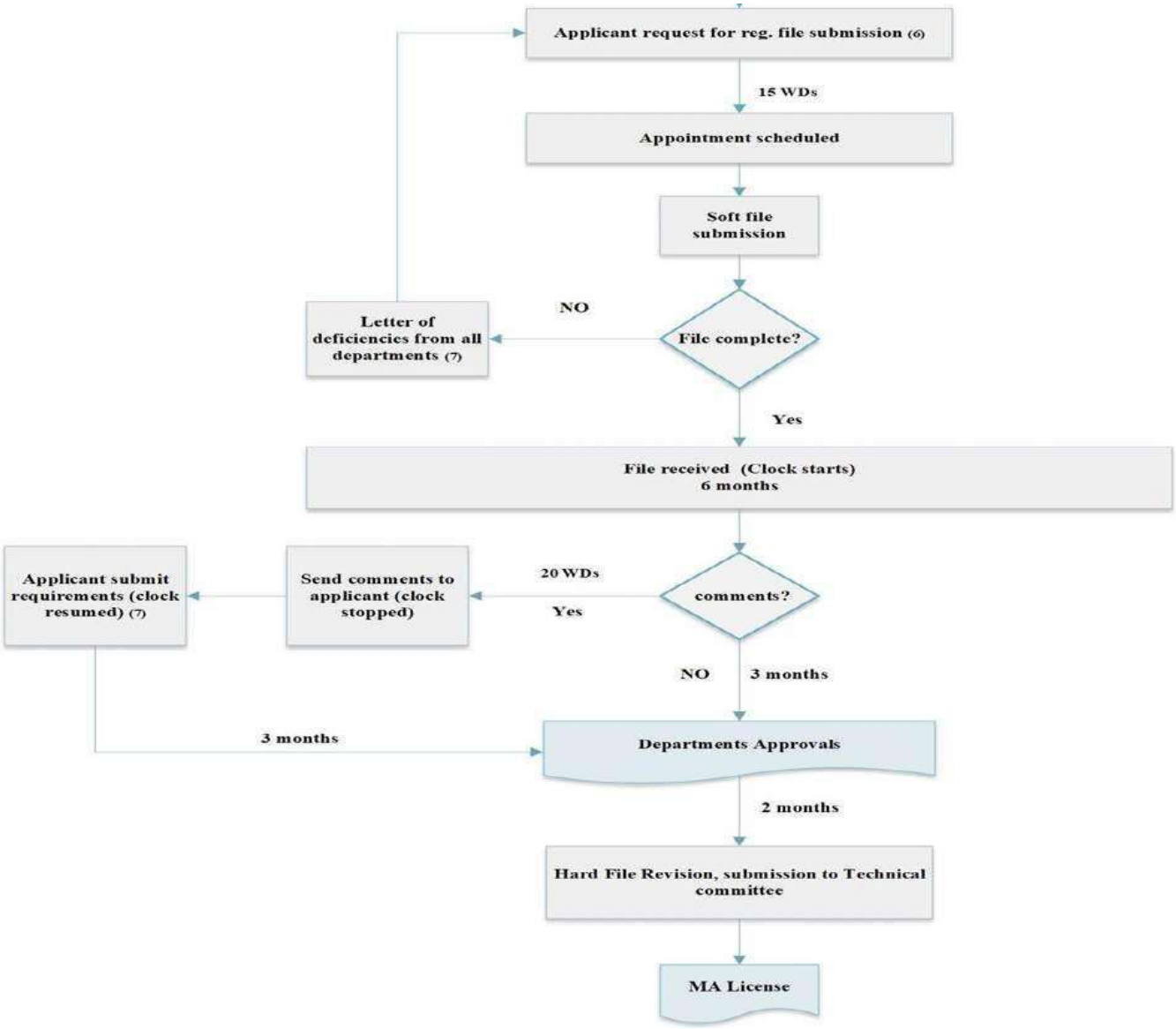




- Assessment timelines start from receiving complete files from applicants.
- Applicant has the right to:
  (1) Reply to the registration request requirements within 3 months.
  (2) Submit to Trade Name unit within 15WDs from registration request approval.
  (3) Apply for the Bioequivalence unit (if any) to determine the type of the required study. (Optional).
  (4) Submit the complete registration file within 30 WDs from registration request approval or from company approval date on pricing to the administration of human pharmaceuticals regulatory affair (evaluation unit of registration file for imported human pharmaceuticals).
  (5) Reply on letter of deficiencies from all departments within 3 months (renewed once).

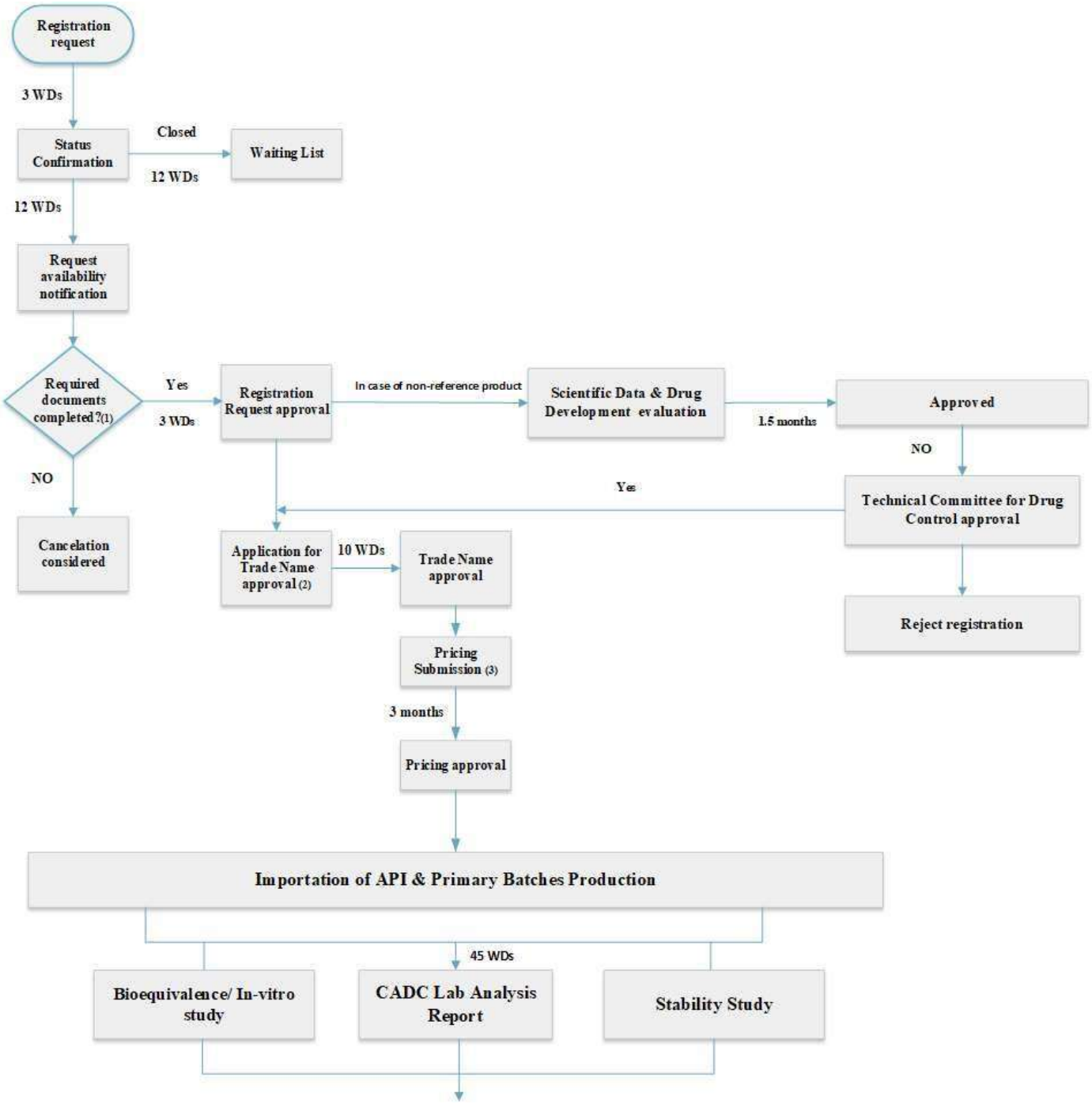
Ministerial Decree 820/2016 – Imported (CTD) Drugs Flowchart with assessment timelines

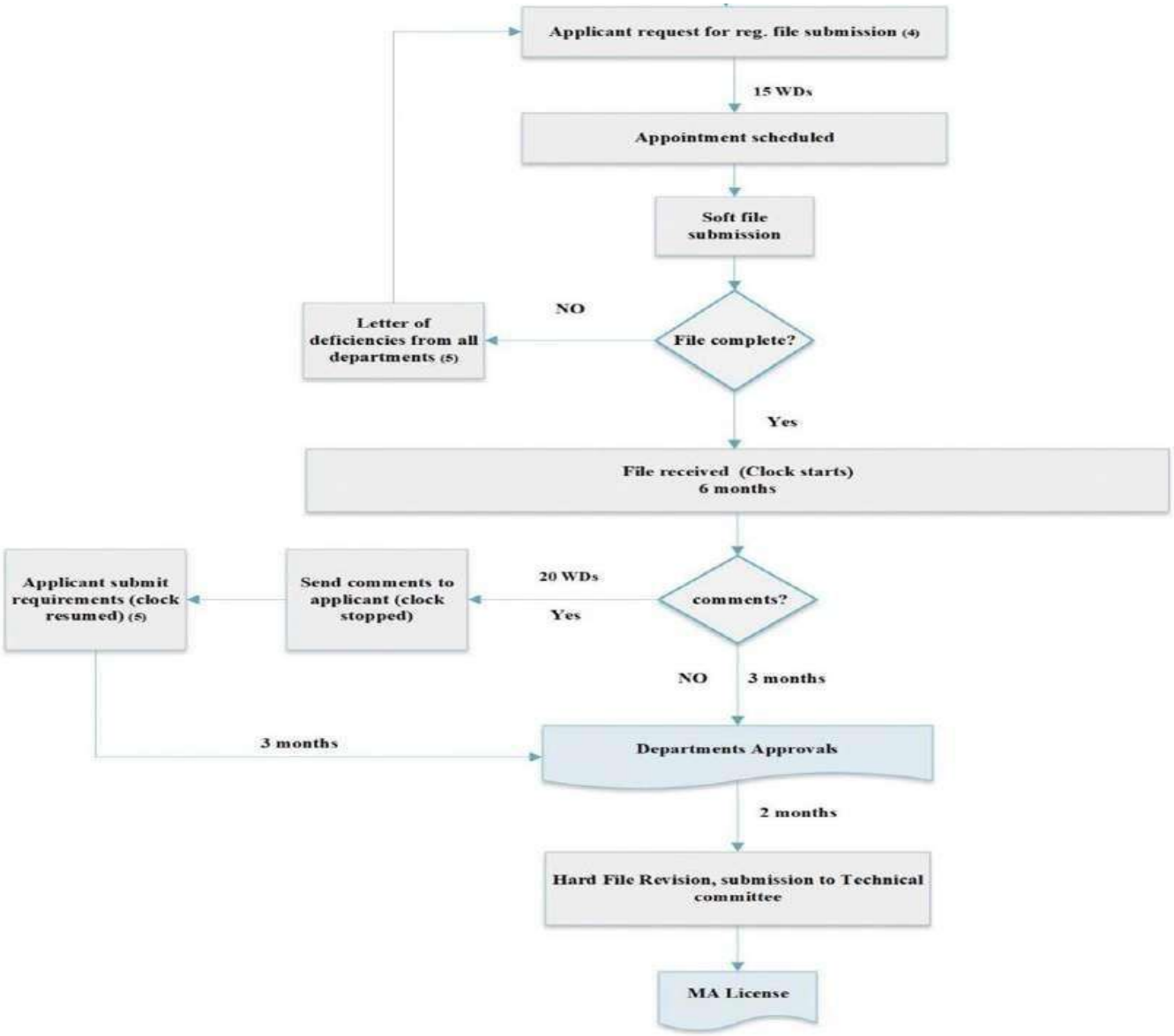




- Assessment timelines start from receiving complete files from applicants.
- Applicant has the right to:
  (1) Reply to the registration request requirements within 3 months.
  (2) Submit required documents from technical committee in case of product from non-reference country within 2 months.
  (3) Submit to Trade Name unit within 1.5 months from registration request approval.
  (4) Submit to Pricing department within 1.5 months from Trade Name approval.
  (5) Apply for the Bioequivalence unit (if any) to determine the type of the required study. (Optional).
  (6) Submit the complete registration file within 2 months from trade name approval or from company approval from pricing to the administration of human pharmaceuticals regulatory affair (evaluation unit of registration file for imported human pharmaceuticals).
  (7) Reply on letter of deficiencies from all departments within 3 months (renewed once).

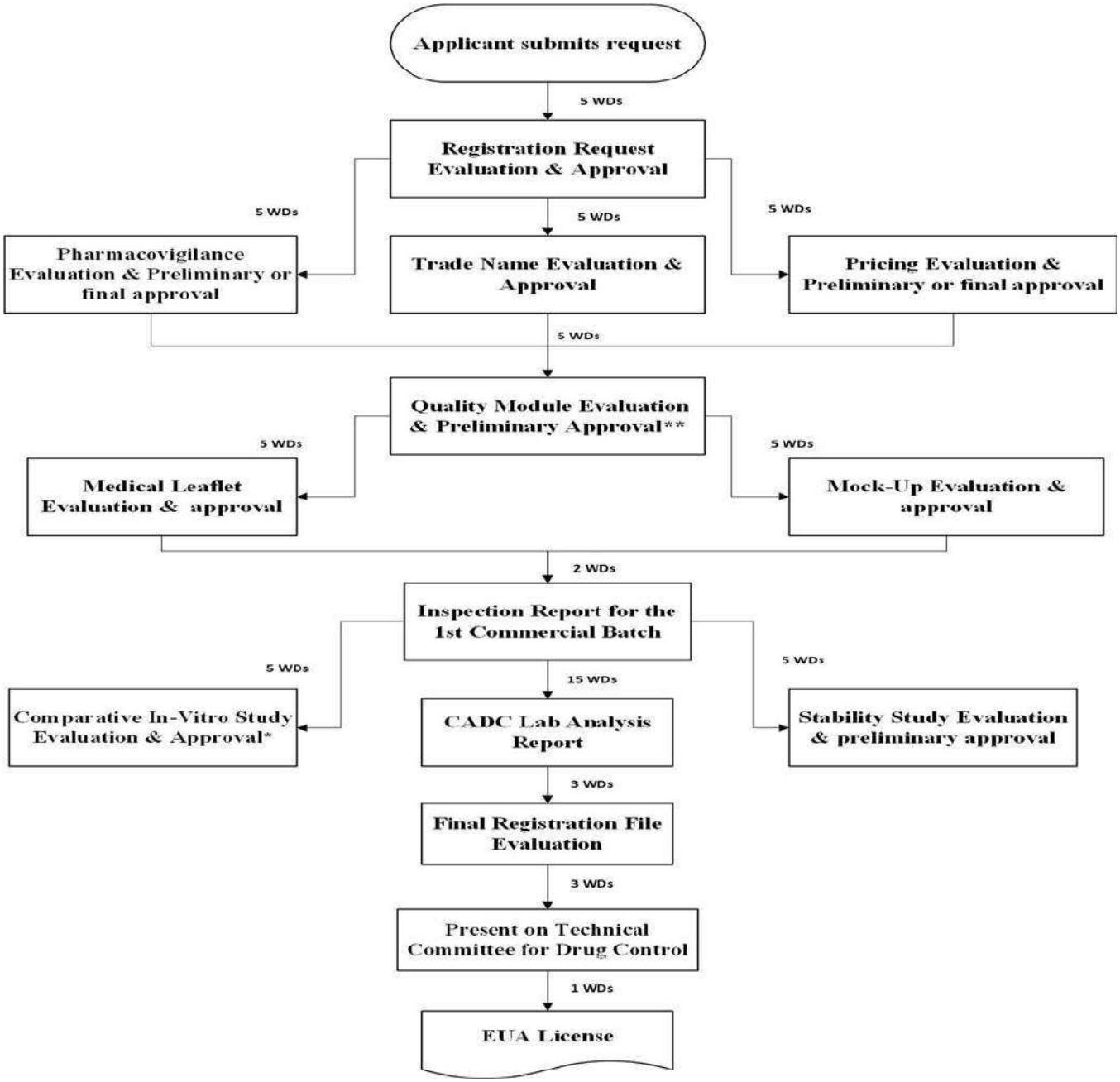
Ministerial Decree 820/2016 – Local (CTD) Drugs Flowchart with assessment timelines





- Assessment timelines start from receiving complete files from applicants.
- Applicant has the right to:
  (1) Reply to the registration request requirements within 3 months.
  (2) Submit to Trade Name unit within 1.5 months from registration request approval.
  (3) Submit to Pricing department within 1.5 months from Trade Name approval.
  (4) Submit the complete registration file 3 years from pricing approval to the administration of human pharmaceuticals regulatoryaffair (evaluation unit of registration file for imported human pharmaceuticals).
  (5) Reply on letter of deficiencies from all departments within 3 months (renewed once).

Emergency Use Approval (EUA) Flowchart with assessment timelines



- Assessment timelines start from receiving complete files from applicants
- If the time of release of the batches intersected by the zero or 3rd or 6th month of the accelerated stability studies, the batches will not be released till EDA approves the stability data for the intersected time interval.

*Bioequivalence study approval is a condition for the commercial batch release (if applicable).