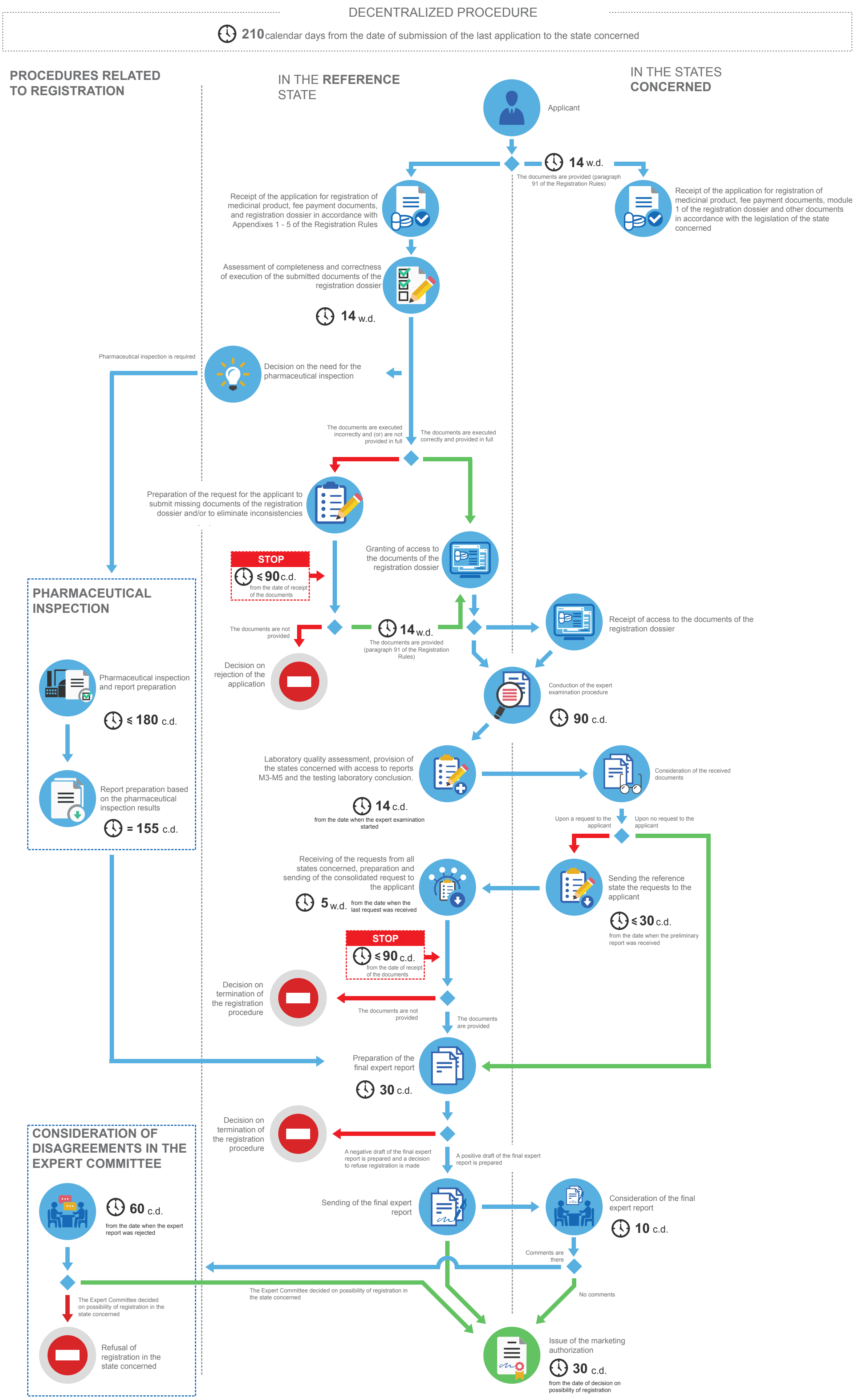
DECENTRALIZED PROCEDURE
210 calendar days from the date of submission of the last application to the state concerned
PROCEDURES RELATED TO REGISTRATION
IN THE REFERENCE STATE
IN THE STATES CONCERNED
Applicant
14 w.d.
The documents are provided (paragraph 91 of the Registration Rules)
Receipt of the application for registration of medicinal product, fee payment documents, and registration dossier in accordance with Appendixes 1 - 5 of the Registration Rules
Receipt of the application for registration of medicinal product, fee payment documents, module 1 of the registration dossier and other documents in accordance with the legislation of the state concerned
Assessment of completeness and correctness of execution of the submitted documents of the registration dossier
14 w.d.
Pharmaceutical inspection is required
Decision on the need for the pharmaceutical inspection
The documents are executed incorrectly and (or) are not provided in full
The documents are executed correctly and provided in full
Preparation of the request for the applicant to submit missing documents of the registration dossier and/or to eliminate inconsistencies
STOP
≤ 90 c.d.
from the date of receipt of the documents
Granting of access to the documents of the registration dossier
PHARMACEUTICAL INSPECTION
The documents are not provided
14 w.d.
The documents are provided (paragraph 91 of the Registration Rules)
Receipt of access to the documents of the registration dossier
Decision on rejection of the application
Pharmaceutical inspection and report preparation
≤ 180 c.d.
Conduction of the expert examination procedure
90 c.d.
Report preparation based on the pharmaceutical inspection results
= 155 c.d.
Laboratory quality assessment, provision of the states concerned with access to reports M3-M5 and the testing laboratory conclusion.
14 c.d.
from the date when the expert examination started
Consideration of the received documents
Upon a request to the applicant
Upon no request to the applicant
Receiving of the requests from all states concerned, preparation and sending of the consolidated request to the applicant
5 w.d.
from the date when the last request was received
Sending the reference state the requests to the applicant
≤ 30 c.d.
from the date when the preliminary report was received
STOP
≤ 90 c.d.
from the date of receipt of the documents
Decision on termination of the registration procedure
The documents are not provided
The documents are provided
Preparation of the final expert report
30 c.d.
Decision on termination of the registration procedure
A negative draft of the final expert report is prepared and a decision to refuse registration is made
A positive draft of the final expert report is prepared
CONSIDERATION OF DISAGREEMENTS IN THE EXPERT COMMITTEE
Sending of the final expert report
Consideration of the final expert report
10 c.d.
60 c.d.
from the date when the expert report was rejected
Comments are there
The Expert Committee decided on possibility of registration in the state concerned
No comments
The Expert Committee decided on possibility of registration in the state concerned
Refusal of registration in the state concerned
Issue of the marketing authorization
30 c.d.
from the date of decision on possibility of registration