EXPERT EXAMINATION AND REGISTRATION OF MEDICINAL PRODUCT IN THE **REFERENCE** STATE

210 calendar days

Submission of documents

Assessment of completeness and correctness of the execution

Request receipt

14 w.d.

Termination of the registration procedure in case of no response to the request

STOP

≤ **90** c.d.

from the date of receipt of the documents

PHARMACEUTICAL INSPECTION

Decision on the need for the pharmaceutical inspection

Pharmaceutical inspection and report preparation

Report preparation based on the pharmaceutical inspection results

Expert examination procedure, preparation of the expert report M3-M5 and conclusion of the testing laboratory.

180 c.d.

Final expert report

Refusal to issue the marketing authorization

10 c.d.

Issue of the marketing authorization

MUTUAL RECOGNITION PROCEDURE

EXPERT EXAMINATION AND REGISTRATION OF MEDICINAL PRODUCT IN THE STATE **CONCERNED**

100 calendar days

Inconsistency of the submitted documents with the Registration Rules and/or non-confirmation of the charge (fee) payment

Submission of the documents to the authorized body of the state concerned

14 w.d.

Termination of the registration procedure

The applicant's request to the authorized body of the reference state on providing access to the registration dossier and the expert report

5 w.d.

50 c.d.

Providing access to the documents through the integrated system

50 c.d.

No response to the request

Request to the applicant in the form of comments from the state concerned (if any)

10 w.d.

Termination of the registration procedure

STOP

≤ **90** c.d.

from the date of receipt of the documents

The authorized body received the response to the request

20 c.d.

Conclusion on the possibility of recognizing the expert report

Positive

10 w.d.

Negative

Consideration of disagreements in the Expert Committee

Issue of the marketing authorization