

Timelines: CP + DCP + MRP

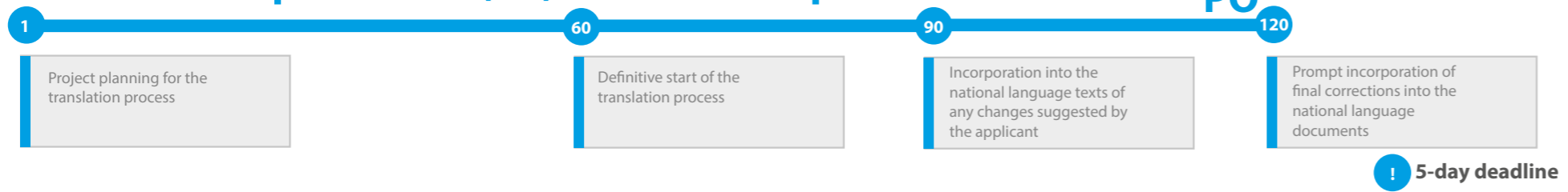


Day of submission

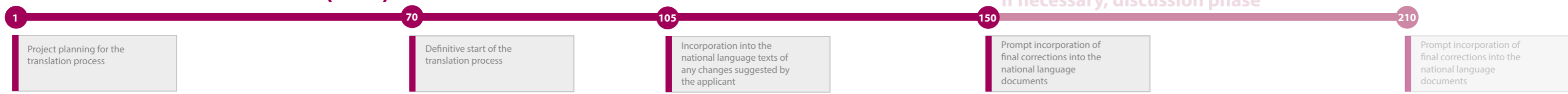
Centralised procedure (CP): Normal duration of the procedure



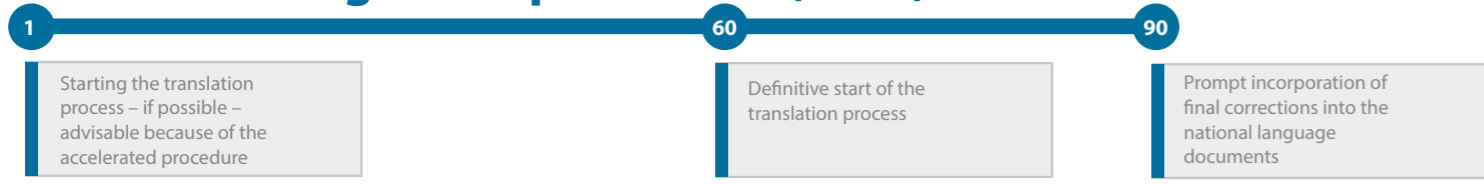
Centralised procedure (CP): Accelerated procedure



Decentralised Procedure (DCP)



Mutual recognition procedure (MRP)



NORMAL DURATION OF THE PROCEDURE (CP)

The procedure normally lasts 180 or 210 days.

Day of submission

The applicant should inform mpü about the submission and send in the documents to be translated. This enables reliable planning of the process and resources. If it is possible and feasible, the translations can be started at this stage.

Project planning for the translation process

Day 80

The applicant submits the first version of the assessment report from the rapporteur/co-rapporteur. Any requirements to make changes to the SmPC, package leaflet or labelling should be forwarded to mpü. The translations should be carried out from day 80 at the latest, taking any comments in the assessment report into account.

Start the translation process if possible/feasible

Day 120, start of the clock-off phase

The applicant receives the list of questions (LoQ). If there have been any requests to make changes to the SmPC, package leaflet or labelling, the applicant should inform mpü. When submitting the response package, the applicant should forward the changed source text.

Definitive start of the translation process

Day 180 or 210, if outstanding issues still have to be clarified

Forwarding of the Positive Opinion to the applicant. **After the Positive Opinion, only final corrections should now be made.**

Prompt incorporation of final corrections into the national language documents

ACCELERATED PROCEDURE (CP)

The procedure takes 90 days plus 30 days for reviewing a response package

Day of submission

The applicant should inform mpü about the submission and send in the documents to be translated. This enables reliable planning of the process and resources. If it is possible and feasible, the translations can be started at this stage.

Project planning for the translation process

Day 60

The applicant submits the first version of the assessment report from the rapporteur/co-rapporteur. Any requirements to make changes to the SmPC, package leaflet or labelling should be forwarded to mpü. The translations should be carried out from day 60 at the latest, taking any comments in the assessment report into account.

Definitive start of the translation process

Day 90, start of the clock-off phase

The applicant receives the list of questions (LoQ). If there have been any requests to make changes to the SmPC, package leaflet or labelling, the applicant should inform mpü. When submitting the response package, the applicant should forward the changed source text.

Incorporation into the national language texts of any changes suggested by the applicant

Day 120

Forwarding of the Positive Opinion to the applicant. **After the Positive Opinion, only final corrections should now be made.**

Prompt incorporation of final corrections into the national language documents