

TECHNICAL AND LINGUISTIC LABELING REVIEWS DURING THE EU CENTRALIZED PROCEDURE

DAY 10 | DAY 140 | DAY 150 | DAY 180 | DAY 181 | DAY 210 | DAY 215 | DAY 229 | DAY 235

PRE-OPINION

Technical Labeling Reviews for compliance with QRD templates, SmPC guidance, etc.

English languages product information only.

DAY 10 TO DAY 150

No translations.

English product information only.

CHMP OPINION

CHMP meetings, oral explanations (as needed) and date of opinion on Day 210.

English languages product information only.

DAY 180 TO DAY 210

Operational window for initial frontloaded translations.

POST-OPINION

Linguistic Review Process and Member State QRD review of translated product information.

All official EU languages of product information.

DAY 210 TO DAY 215

Official regulatory window of translations.

DAY 215 TO DAY 235

Member state QRD review of translations and agency review of implementation.