Submission of the Application to the Coordination Unit (PEI, AEMPS and FAGG-AFMPS using the following email address: sns@fagg-afmps.be)

Day -30

To Day -20

To Day -10

Day 0

35 Days

Day 20

To Day 20

Day 0

35 Days

START OF THE PROCEDURE
Submission of the complete application by the Applicant. The lead NCA will send the link for the meeting between the NCAs and the Applicant and the template for the minutes to the participating NCAs and to the Applicant.

VALIDATION OF SNSA by the Coordination Unit (PEI, AEMPS or FAGG-AFMPS). One of them will contact the NCAs proposed by the Applicant and confirm with them their participation and the proposed dates for the TC (by doodle).

Day 55

Evaluation of the information by the lead and participating NCAs

Day 65

Day 90

DEADLINE for the Applicant to submit any missing information in order to provide the complete application to the NCAs. The fees to the lead and participating NCA must be paid according to their national fee regulations. NCAs will check the documentation and the lead NCA will contact the Applicant asking for any missing documentation if needed.

NCAs and Applicant SNSA MEETING

END OF THE PROCEDURE
The lead NCA will send the final advice report to the Applicant together with the feedback survey for completion. The final advice report will also be sent to the involved NCAs.

Role of PEI (Paul-Ehrlich-Institut), AEMPS (Spanish Agency of Medicines and Medical Devices) and FAGG-AFMPS (Belgium federal Agency for medicines and health products) as Coordination Unit

Roles of the Lead National Competent Authority (NCA), the participating NCA(s) and the Observer

Review of the meeting minutes by Lead and participating NCAs. The Observer NCA will only check the participants list and include only information about National legal requirements if needed.