



Centralised Procedure (CP) and National Procedure (NP)

How medicines obtain their first marketing authorisation

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Agenda

- Why registration matters
- CP versus NP
- Strategic preparation before submission
- Submission and validation
- Scientific assessment
- Questions from authorities
- Approval and post-approval transition
- Key lessons learned



Why Do We Need Registration?

- Developing a medicine creates knowledge.
- Registration demonstrates to regulators that the knowledge is sufficient to support safety, quality and efficacy.

QUALITY



SAFETY



EFFICACY



BENEFIT-RISK



NP versus CP

NP

- One dossier
- One national authority
- Result: MA in a single Member State



CP

- One dossier
- EMA coordinated assessment
- European Commission decision
- Result: MA in all EU/EEA countries



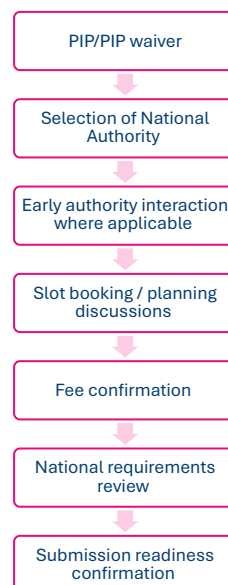
Strategic Preparation Before Submission

Are We Ready to Submit?

- ✓ Correct procedure selected
- ✓ Scientific Advice considered
- ✓ PIP obligations fulfilled (where applicable)
- ✓ Regulatory strategy agreed
- ✓ Dossier complete (Modules 1-5)
- ✓ Manufacturing sites with GMP or inspection-ready
- ✓ Submission timing aligned with authorities



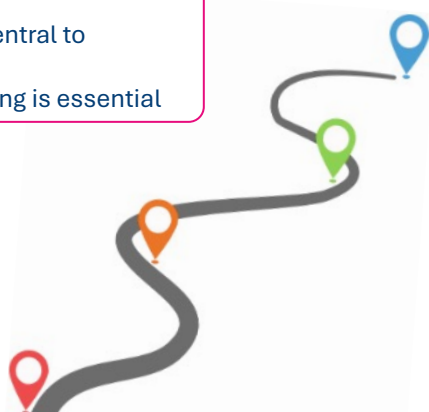
NP: Pre-Submission Activities



CP: Pre-Submission Activities

Key messages:

- EMA interaction starts well before Day 1
- Rapporteurs are central to assessment
- Submission planning is essential



Scientific Advice, PIP

Eligibility confirmation

Letter of Intent

Rapporteur / Co-Rapporteur appointment

Pre-submission interaction

Submission

Which Products Must Use the Centralised Procedure?



Mandatory CP

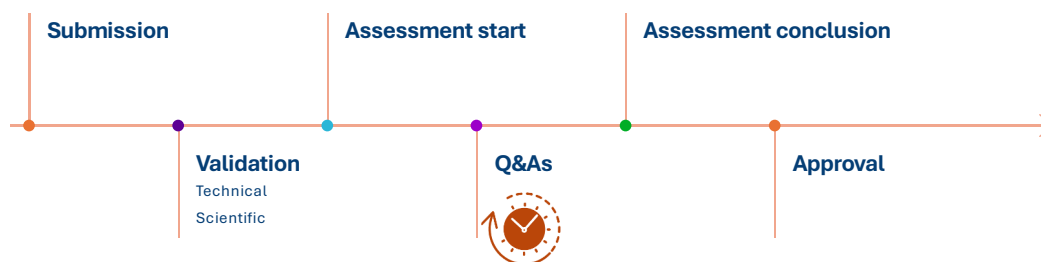
- Biotechnology-derived medicinal products
- Advanced Therapy Medicinal Products (ATMPs)
- Orphan medicinal products
- Certain products containing new active substances for specified therapeutic areas (cancer, HIV...)

Optional / Eligible CP

- Significant innovation
- EU public health interest
- Certain other products meeting eligibility criteria



What happens after submission?

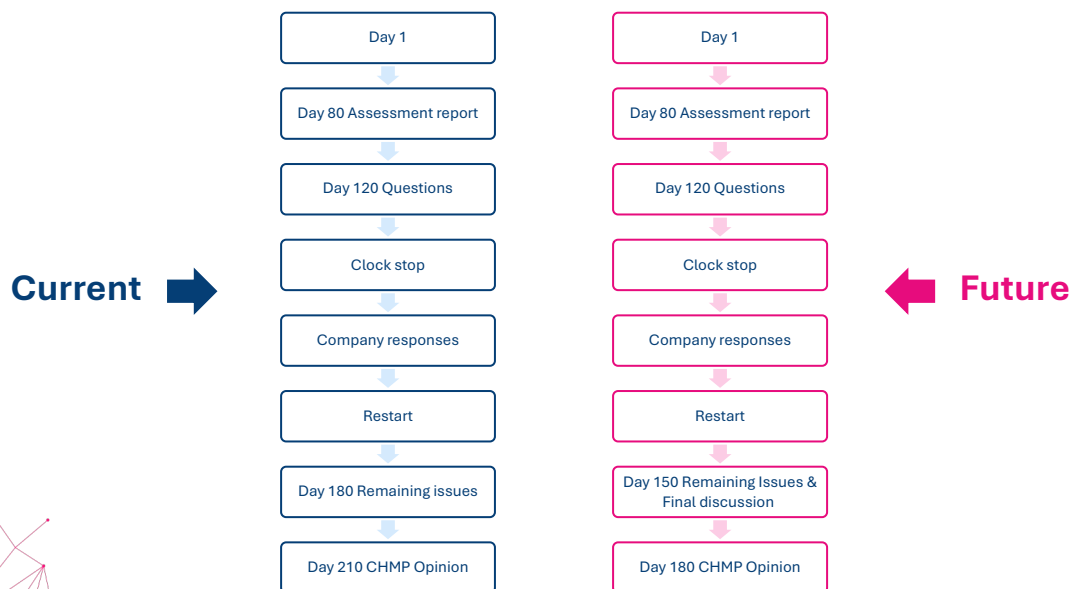


Submission & Validation

Validation answers:
Is the application administratively complete?



How to Read the CP Timetable



Questions from the Regulator

- Questions & Comments
 - Are expected & normal
 - Improve understanding
- What companies need:
 - Subject matter experts
 - Coordination
 - Clear responses
 - Strong project management
- Some questions can be anticipated and prepared for before they arrive



Approval Is Not the End

For NP

- National authorization

For CP

- CHMP Opinion
- Translations & Linguistic Review
- European Commission Decision

For both:

- Commitments and post-approval measures
- Regulatory life cycle start



What Makes a Successful Registration?

Science

- Robust data

Strategy

- Correct procedure
- Proper planning

Communication

- Health authority interactions
- Questions and responses

Execution

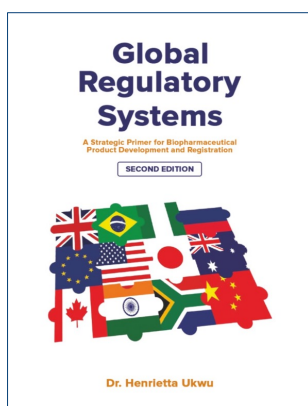
- Timelines
- Documentation
- Coordination

Successful registrations are rarely won during assessment. They are usually won during preparation.



Thank You

Practical regulatory knowledge and career
development resources



Local networking, knowledge exchange and
professional development

RAPS Czech LNG