

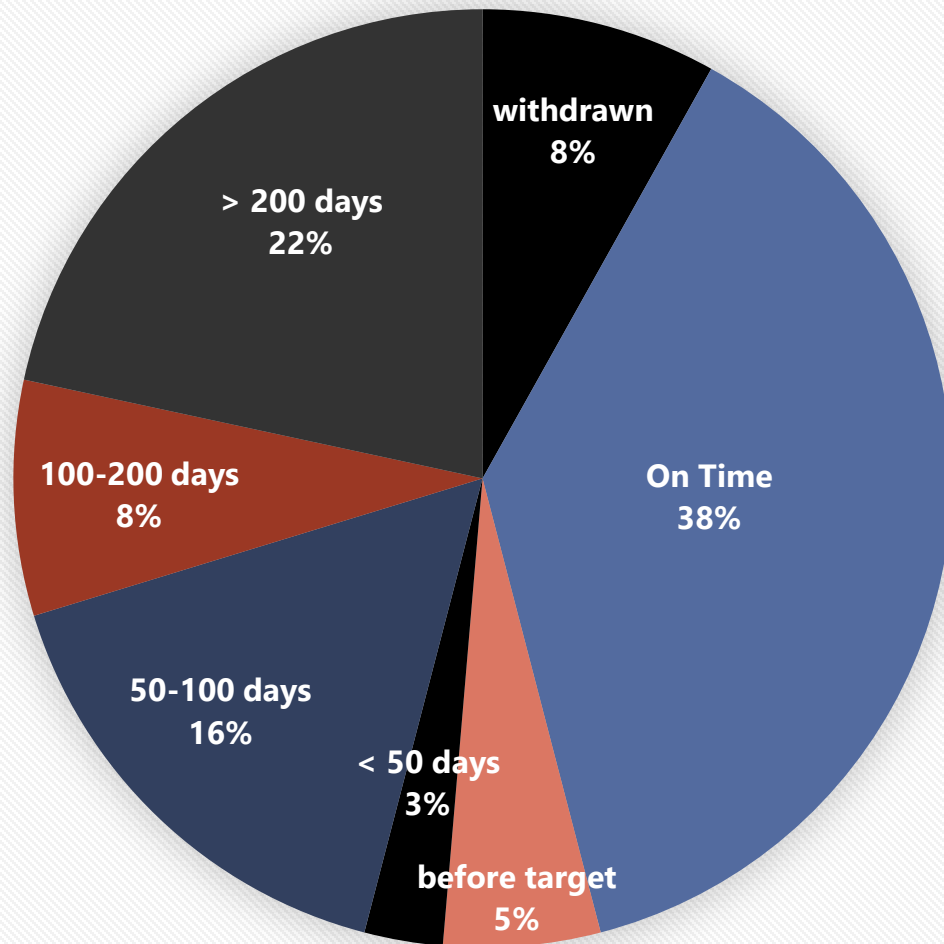
# Joint HMA/EMA multi-stakeholder workshop on submission predictability

## Views & concerns from Member States **Case studies**

# AT Rapporteurships

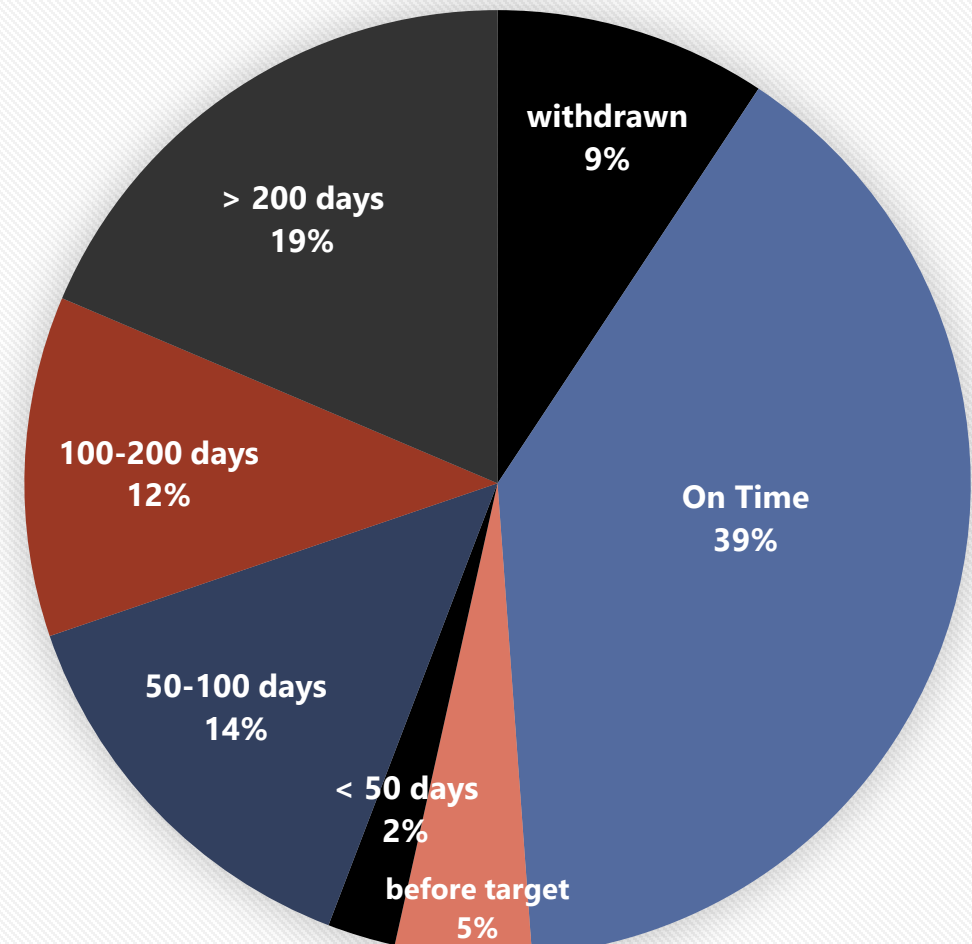
## Postponements and shifts of Rapporteurships starting in 2022/2023

AT = Rapporteur/Corapporteur



Rapporteur/Corapporteur = 37

AT procedures incl. multinational procedures



Rapp/Corapp + MNATS (37 + 6)

# Statistics from another NCA

- On average **8 months** delays, maximum **60** Months
- 53% to 90% (with different indications in separate divisions) of procedures are delayed (if compared with submission dates initially shared with the Letter of Intent)
- Accumulation of procedures (5 in parallel in one team, ...)
- Issues with stepwise delays: 3 times for 2-3 months, 10x within 4 years,

# Case Report – CP submission date postponed twice

**04.08.2023 – EMA asks for confirmation of intended submission date of 02/11/2023**

**21.08.2023 – Submission date of 02/11/2023 confirmed by company**

**13.09.2023 – Company postpones submission date to 21/02/2024**

**NCA: must reassign its assessor allocation to all procedures during this period**

**23.11.2023 – EMA asks for confirmation of postponed submission date of 21/02/2024**

**04.12.2023 – Submission date of 21/02/2024 confirmed by company**

**29.01.2024 – Company postpones again submission date to 28/06/2024 due to ...new delay due to missing feedback regarding acceptability of (product) name, logistic issues with importation and testing of product in Europe, emergency outbreak in third country**

**NCA: must reassign its assessor allocation to all procedures during this period**

**03.04.2024 – Submission date of 28/06/2024 confirmed by company**

**NCA: NCA fully booked - wait and see: other delays of acquired CPs expected**

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## Views & concerns from Member States

Impact on the network when changing submission date,  
and potential consequences for industry

**Ingrid Landberg**

**Swedish Medical Products Agency**

# Swedish MPA 12 months submission statistics

Initially planned submissions between 2023-06 and 2024-06, where Sweden was appointed CHMP/CAT/CVMP Rapporteur/Co-Rapporteur or PRAC Rapporteur:

A total of 33 submissions expected according to initially planned submission dates

- 25 submissions came as planned
- 7 submissions were delayed, all of these were delayed more than once by one to several months
- 1 submission was withdrawn
- In addition, 3 submissions from previous years came in

# Recent SE/DK examples of submission date changes

Product type	Role	Submission expected	Comment
NCE	SE CHMP-Rapp (MNAT with LT)  DK CHMP Co-rapp (MNAT with CZ)	Dec 2024 Sep 2024 Jun 2024 agreed to Aug 2024 Jan 2024 Sep 2023	Five NCAs affected
NCE	SE CHMP-Rapp	Q1 2025 Nov 2024 Jul 2024	
Vaccine	SE CAT/CHMP Rapp	May 2027 Mar 2025 Jun 2024	
NCE	DK CHMP Rapp	Withdrawn Sep 2024 April 2024 May 2023	Due to change of sub date in April 2024 an MNAT had to be formed.

# Consequences of poor predictability for the NCAs

- NCAs do not have an unlimited number of experts available.
- AGES and MPA experts from all disciplines work on national, MRP/DCP procedures and scientific advices in addition to centralised procedures.
- Each case of delay or withdrawal has an impact on the resources of all assigned rapporteurs.
- The use of multinational teams is necessary to help the system, but increases the complexity even further, and ties up resources that could be used for full team nominations.



# Consequences of poor predictability for the NCAs

- Planning and resource allocation impossible – constant reallocation need.
  - Administrative burden increased at both NCA and EMA.
  - Vacations need to be changed, cancelled or interrupted. Stress and overtime.
- Unacceptably high workload when several submissions are often moved to the same period.
- Return of assigned procedures that can no longer be processed due to resource bottlenecks.
  - New Co-/Rapporteur must be sought, or a multinational team must be formed.
- Lower trust in the system at the NCAs.
- Overbook or “play safe”?

# Potential consequences for industry

- Assessor resources are tied up - reluctance to nominate for additional submissions, which means the full capacity of the network for rapporteurships is not used, when submissions are delayed or withdrawn.
- Strained resources in the network - difficult to assign rapporteurs for all applications.
- The assigned rapporteur may need to step down at a late stage.
- Inefficiency of the system increases costs.

# Ideas to improve the situation

- More mature applications. Pivotal studies completed before submission.
- More realistic submission dates in Lol / Better adherence to planned submission dates.
- Awareness of applicants of the need for early communication about arising submission delays.
- Improved Clock Stop predictability.
- Improved predictability (communication) of type II variation and extensions submissions.
- [Best practice guide - Final \(europa.eu\)](#)  
*“If an intended submission date is not met, a discussion should be initiated with the EMA/NCAs to assure the availability of assessment teams and explore the need for an adjustment of the submission date”*

**Thank you!**  
**Happy to discuss your proposals!**