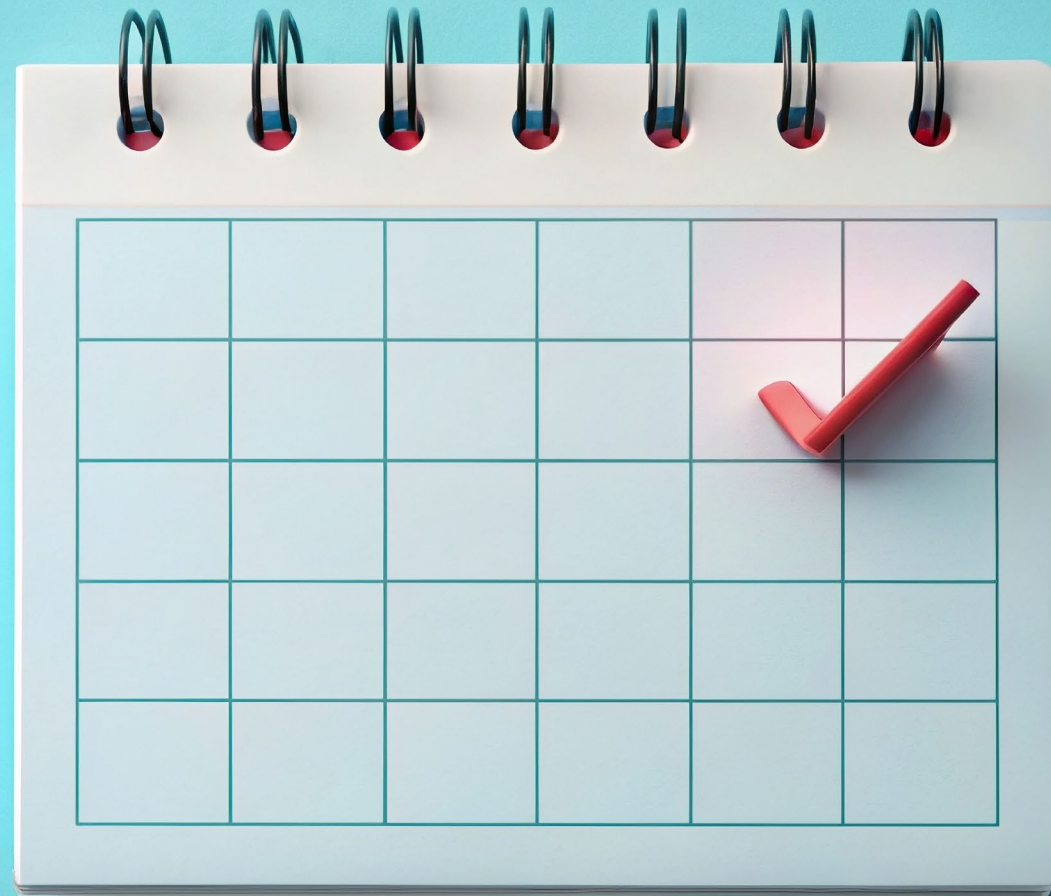


Update on Rapporteur appointments

Alberto Ganan Jimenez

Head of Head of Committees and Quality Assurance



Outline of topics

- Overview of the Rapporteurs' appointment and resource impact when changing submission date.
- Points for consideration
- New fee regulation - provisions for pre-submission activities and changes in submission dates for MAA

Overview of the Rapporteurs' appointment and resource impact when changing submission date

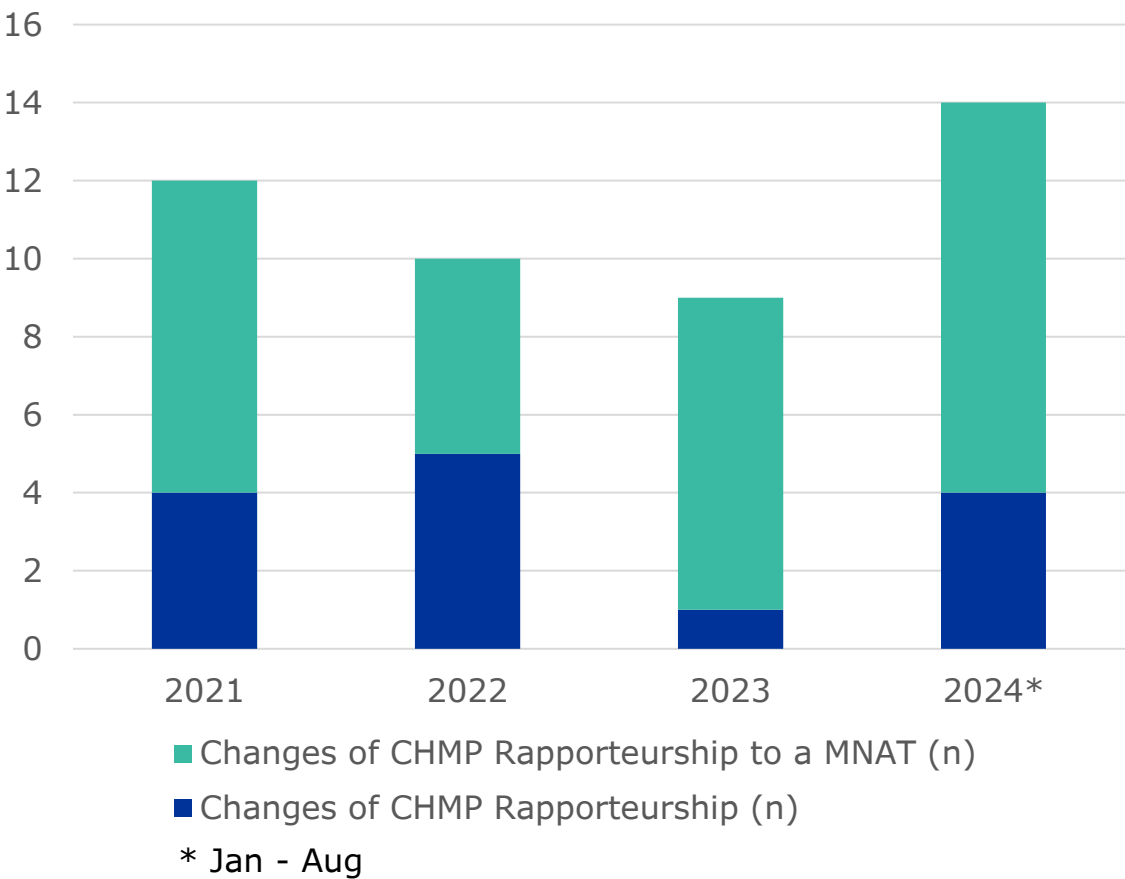
- Following receipt of a Letter of Intent, the Rapporteurship appointment takes place 6-7 months prior to intended submission date.
- The Agency has an internal process to identify the best available expertise within the network for Rapporteurship appointment by CHMP. This process entails:
 - Expression of interest by NCAs for Rapporteurship of a product/procedure or for participating as part of a Multinational Assessment Team (MNAT).
 - Appointment of Rapporteurs by CHMP and PRAC, in consultation with the respective chairs, as appropriate, including the CAT chair for ATMPs.

The delay in submissions triggers changes to Rapporteurship

Changes in Rapporteurship for MAAs

- In the last 4 years, the delays in submissions resulted in a change of Rapporteurship in **5-8%** of the appointments.
- The replacement of Rapporteurs was associated with **longer delays** (av. 19 months, [12-37]) while changes of Rapporteur into a MNAT is linked with shorter delays (av. 9 months, [1-90]).

	2021	2022	2023	2024
Total Rapporteurships MAAs per year (n)	210	193	190	171
% Rapporteurship changes	5,7%	5,2%	4,2%	8,2%



Points for consideration

- Rapporteurs plan and allocate their resources according to the planned submission dates
- The delays have a negative impact on the allocated resources by NCAs for the assessment of the MAA.
- EMA is closely monitoring the impact of delays in submission in Rapporteurship appointment.
- If number of changes in Rapporteurship increases, additional measures could be considered for certain applications with more than one postponement or with long delays such as the automatic release of assigned Rapporteurs or the agreement of the new exact proposed submission date with Rapporteur.

New fee regulation

Provisions for pre-submission activities and changes in submission dates for MAA

The new fee regulation establishes new fees for pre-submission activities from 1.1.2025 (Annex IV, point 3 of [Regulation \(EU\) 2024/568](#))

3. Pre-submission requests by a prospective applicant prior to a potential submission of an application for a marketing authorisation falling within the scope of the centralised procedure

3.1. A fee of EUR 8 600 shall apply to each eligibility request submitted with a notification of intention to submit an application for a marketing authorisation falling within the scope of Regulation (EC) No 726/2004 or the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation (EU) 2019/6. The fee shall cover any costs related to pre-submission activities up until the potential submission of the marketing authorisation application. The fee shall apply irrespective of whether or not a marketing authorisation application for the concerned product is subsequently submitted. If an eligibility request with a notification of intention to submit an application for a marketing authorisation has not been submitted, the fee shall apply in addition to the applicable authorisation fee.

The remuneration of the competent authority of the Member State, where applicable, shall be EUR 1 600 for the rapporteur and EUR 1 600 for the co-rapporteur.

3.2. Where the applicant changes the intended submission date by more than 60 days, an additional fee of EUR 4 200 shall apply. The additional remuneration of the competent authority of the Member State, where applicable, shall be EUR 800 for the rapporteur and EUR 800 for the co-rapporteur.

New fee regulation 2025

Provisions for pre-submission activities and changes in submission dates for MAA



The submission of the Letter of intent triggers the fee for pre-submission activities (point 3.1, Annex IV, Regulation [2024/568](#))



The letter of intent establishes the intended submission date for the MAA application. This date is the reference for calculation of delays.



Any delay beyond 60 days of the intended submission date declared in the Letter of intent will trigger the fee for 'changes in the intended submission date' (point 3.2, Annex IV, regulation 2027/568).



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you for your kind attention

alberto.ganan@ema.europa.eu

Follow us





Join at slido.com **#Sub25**

Send your questions*

**Questions asked by raising the hand will be prioritised*

Slido questions for industry



Join at slido.com **#Sub25**



Coffee break

We're back in 15'



Join at **slido.com**
#Sub25

