

EUROPEAN  
MEDICINES  
AGENCY

## Updates from EMA on scientific advice

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14th Industry stakeholder platform on research and development support

Presented by Iordanis Gravanis on 3 July 2025  
Scientific Advice Office, Evidence Generation Department, Human Medicines Division, EMA

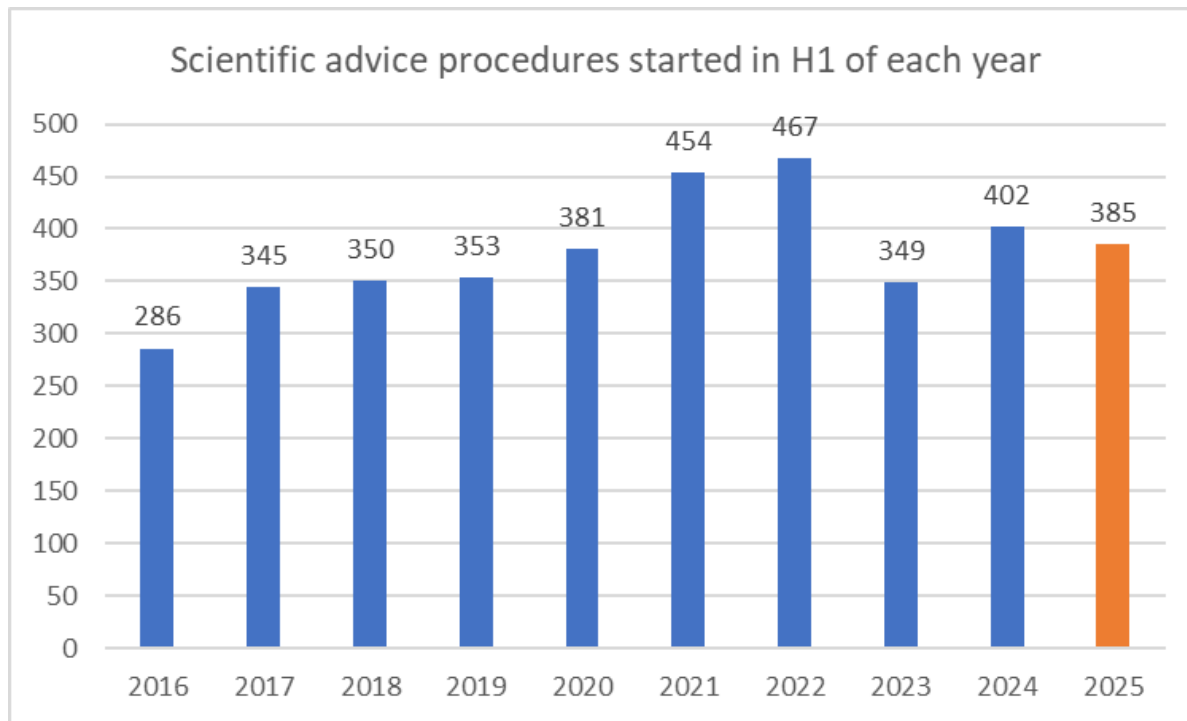
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# Outline

- 2025 scientific advice volumes to date
- Follow-up to latest guidance including on paediatric developments
- Experience with the SAWP/CTCG scientific advice pilot
- Discussion meetings update

## 2025 mid-year scientific advice volumes



# Follow-up to latest guidance updates

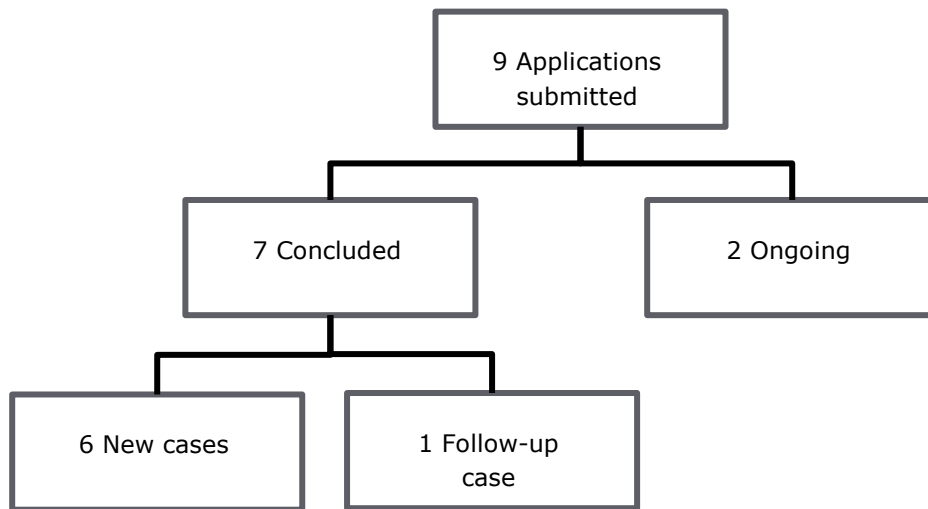
Latest public guidance updates in November 2024 relating to:

- Paediatric scientific advice
- EMA new fee regulation
- Overall webpage content re-structuring to increase reader-friendliness

Experience since then:

- Very rare problems with paediatric scientific advice requests
- High number of applicants missing fee prepayment deadlines which will be enforced from July 7<sup>th</sup> (refer also to relevant warning on the [Requesting scientific advice or protocol assistance from EMA](#) webpage)

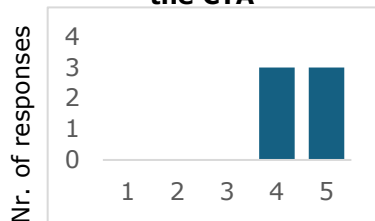
# SAWP-CTCG pilot: analysis of experience to date



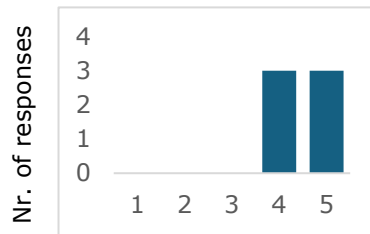
- Cut-off date for interim analysis: 1 year from the launch of the pilot
- Applicant feedback on 6 Responses received

On a scale of 1 to 5 where 1 means 'strongly disagree' and 5 means 'strongly agree' how would you rate the following sentences

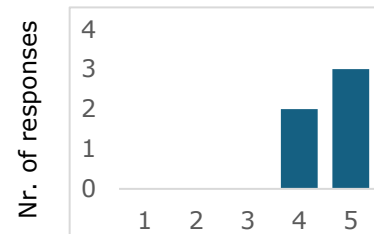
**The SAWP/CTCG advice will assist in the submission of the CTA**



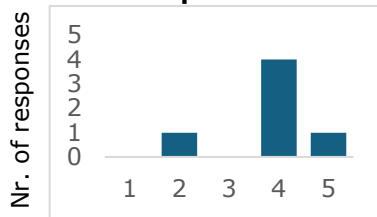
**The SAWP/CTCG advice will assist in the submission of the MAA**



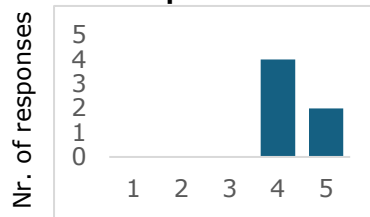
**As a result of this SAWP/CTCG advice, a clearer understanding of the scientific requirements relating to the present CTA has been obtained**



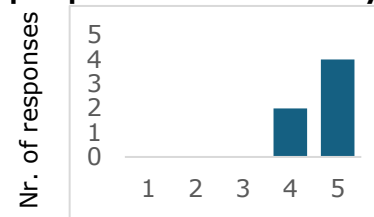
**The advice is expected to result in changes to the submission plan of the CTA**



**The SAWP/CTCG advice has added value as compared to other procedures**

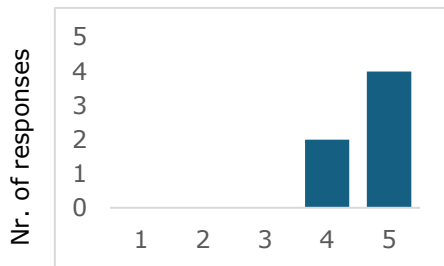


**It is of added value to be able to get the CTA perspective and the MAA perspective simultaneously**

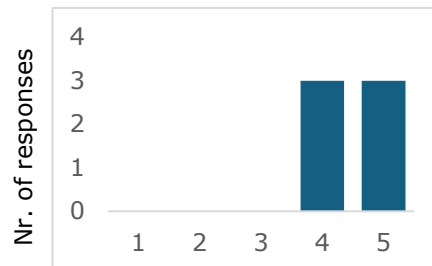


On a scale of 1 to 5, where 1 means 'very dissatisfied' and 5 means 'very satisfied,' how would you rate your satisfaction with the following?

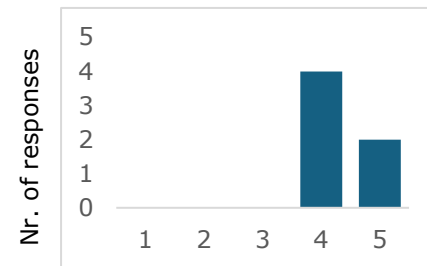
**The application procedure for the SAWP/CTCG advice**



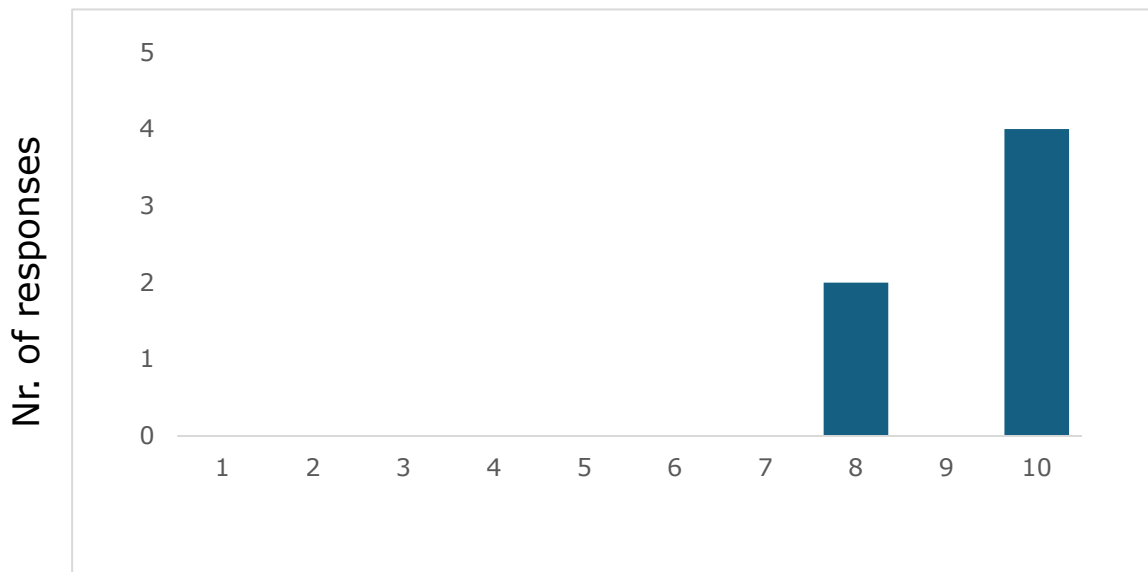
**The communication about the SAWP/CTCG procedure**



**The clarity of the final SAWP-CTCG advice received**



On a scale from 1 to 10 where 1 means 'not at all likely' and 10 means 'extremely likely,' how likely are you to apply again for another SAWP/CTCG advice?





## Conclusion of interim report

- Pilot widely appreciated by Applicants
- Pilot has achieved its target so far
- Appreciation of:
  - early dialogue
  - consistency between CTA and MAA
  - potential to identify issues in advance and to cut-down numbers of RFI in the CTA
- Added value as compared with existing EU-wide scientific advice options (i.e. SNSA, SAWP)
- Bottlenecks/Concerns:
  - participation of MSC
  - maintenance of consistency with CTA assessment

## Next Steps

- Full report once 10 procedures are completed (by end of 2025)
- Reporting to ACT EU (HMA, EMA and EC)
- Requests for entry into the pilot to continue until final decision to cease or continue

## Update on proposals for improving discussion meetings (DMs)

- The SAWP has been focusing on ways to optimise the preparation for and follow-up to discussion meetings
- Although in principle desirable in case of few issues to discuss, an up-front shorter duration of some discussion meetings is no longer actively considered



# Let's discuss!