Updates from EMA on scientific advice

16th Industry stakeholder platform on research and development support

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Outline

- H1 2026 scientific advice volumes
- Briefing document template update
- Progress with pre-payment requirements
- Broad scientific advice
- SAWP/CTCG scientific advice pilot update

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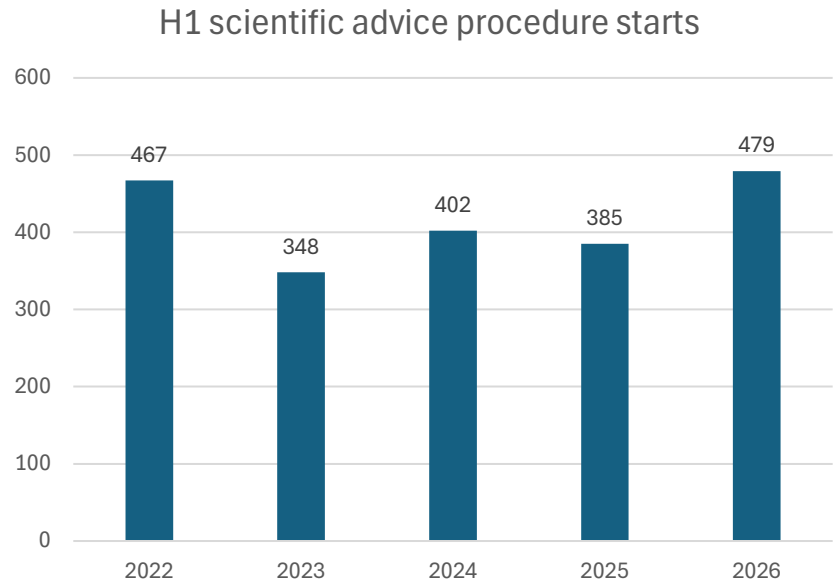
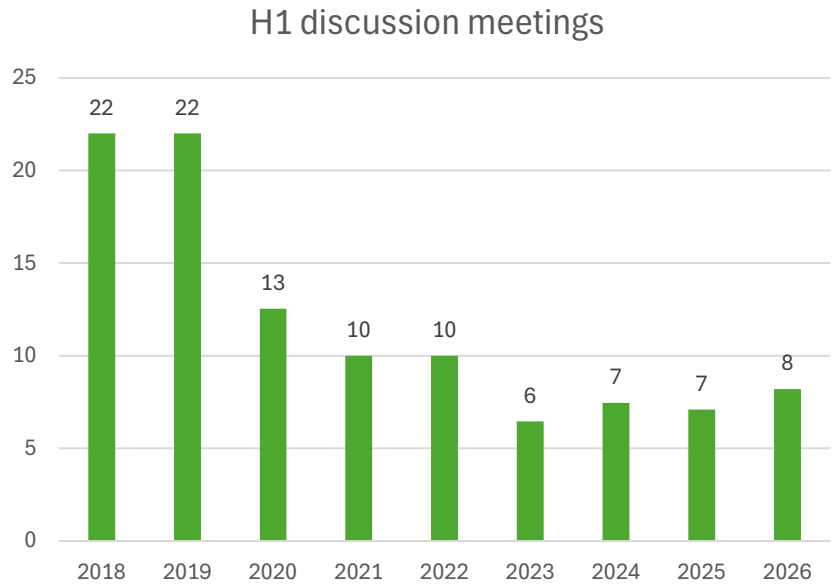
H1 2026 scientific advice volumes





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Briefing document template update

- Additional optional sub-sections on special populations will be going ahead
- Patient-specific section agreed to be an Annex requires additional discussion on the conditions of its use
- Industry proposal for ‘reversal’ of template structure with background information following questions and applicant’s positions is under consideration
- EMA and SAWP are re-thinking the way that advice responses are being drafted
- Implementation of the new template has been postponed until the second and especially the fourth item above have progressed

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Progress with pre-payment requirements

- Implementation of scientific advice 'pre-payment' **at time of validation**, as mandated by Regulation (EU) 2024/568, has created a number of problems
- EMA has decided to move payment at time of initial submission (actual pre-payment) with invoice adjustment at time of procedure start without time pressure
- EMA will be adapting IRIS to implement pre-payment **at submission** (2026 IRIS development focused until now on implementation of MAA and related pre-submission activities): planned implementation by end of 2026
- EMA is also in final stages of IT infrastructure development to allow direct debit for payment of invoices

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Broad scientific advice considerations

- Intended to merely overcome the restriction of '1 product+1 indication/scientific advice request', but slightly mis-used historically also for discussions on product-independent, but still substance-specific (e.g. novel excipient) development aspects
- Proposed at 15th R&D platform meeting for other (substance-independent), multi-sponsor and cross-sector (e.g. chemicals, food) development aspects
- In relation to cross-sector issues, the new pharma legislation (NPL) provides for involvement of other EU authorities and public bodies for the provision of scientific advice
- Reconsideration of the scope of broad scientific advice will take place as part of the NPL implementation
- RPI categories of 'technology' and 'methodology' will be made available soon to use for non-product specific broad scientific advice and qualification, respectively

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SAWP/CTCG pilot update

- Launched in June 2024, 19 applications received to date
- Applicant and EMRN feedback collected via dedicated surveys at one year
  - Expectations of consolidated advice and smoother CTA process
  - Cross-fertilisation between SA/MAA and CT assessors in regulatory discussions but concerns about workload
  - Concerns about MSC engagement and implications for subsequent CTA
  - Concerns about lack of involvement of Ethics Committees and about combined studies* being out of scope
- The pilot continues until further review

* Combined studies are clinical trials for medicinal products combined with clinical investigations of medical devices or performance studies of in vitro diagnostics, SAWP: Scientific Advice Working Party, CTCG: Clinical Trials Coordination Group, EMRN: EU Medicines Regulatory Network, CT(A): clinical trial (application), SA: scientific advice, MAA: marketing authorisation application, MSC: Member State Concerned,

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Thank you

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