Recent developments to address scientific advice capacity and scope

9th Industry stakeholder platform on research and development support

Presented by Iordanis Gravanis on 5 December 2022
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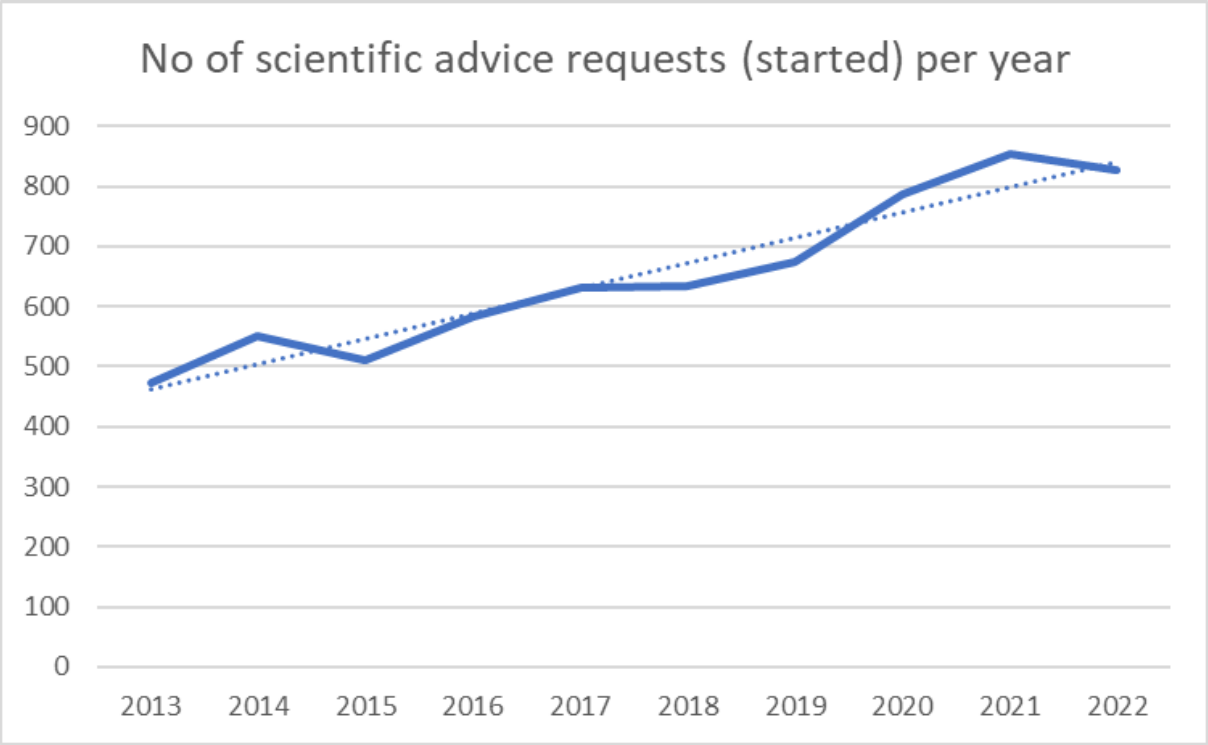
Outline

- Scientific advice capacity and delays
- Briefing Document update
- Public guidance update
- Insight into the future

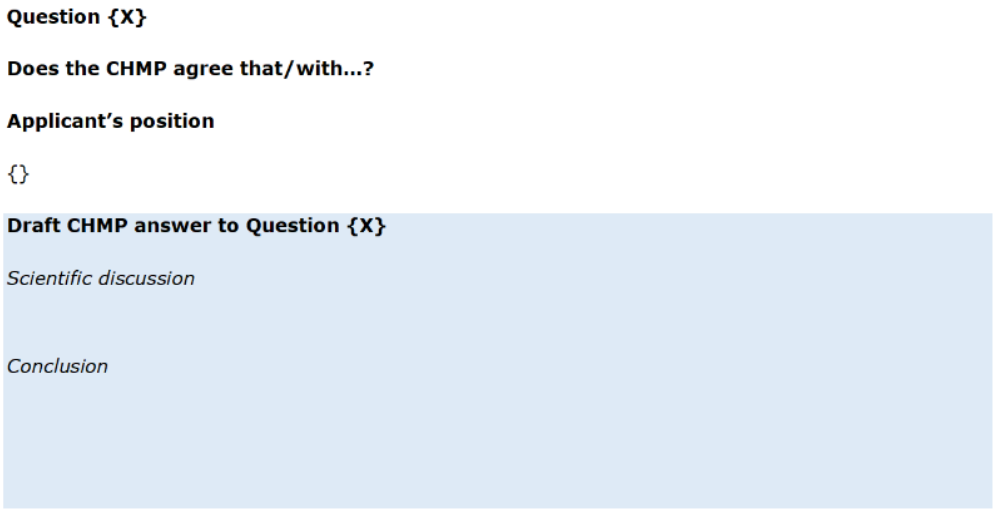
1 9th Industry stakeholder platform on research and development support

2022: a correction year



New scientific advice Briefing Document template

- Integrated Briefing Document/ Assessment Report template
- Sections highlighted in blue for regulatory use only
- Simplified structure for applicants
- Published on 14/10/2022 and its use **becomes mandatory** for submissions as of January 2023



Question {X}

Does the CHMP agree that/with…?

Applicant's position

{}

Draft CHMP answer to Question {X}

Scientific discussion

Conclusion

Update to scientific advice public guidance: what questions not to ask in scientific advice

Questions about the topics below are outside the scope of scientific advice:

- Compassionate use, advanced therapy medicinal product (ATMP) classification, PRIME eligibility, and accelerated assessment
- Adequacy of planned paediatric studies or an overall development plan to support a paediatric indication, which EMA addresses via a PIP submission
- Changes to the key elements of Paediatric Investigation Plan (PIP) measures and paediatric waivers or deferrals, which EMA addresses via a paediatric procedure
- Matters of a purely regulatory nature (please use the 'Submission Details' field in your submission via the IRIS portal)
- Adequacy of existing data for assessment of a regulatory application (e.g. a clinical trial application or marketing authorisation application). However, please include existing data expected to inform the discussion of questions on further development steps in the scientific advice briefing documentation

Update to scientific advice public guidance: what questions not to ask in scientific advice

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Scientific advice for paediatric developments

Questions not to ask in scientific advice:	•**Need (or waiver) for** paediatric-specific formulation, **need (or waiver) for** juvenile animal studies, **adequacy of** proposed studies to support paediatric indication, **adequacy of** overall paediatric development plan, **waiver or replacement** of studies agreed as part of PIP
Questions to (continue to) ask in scientific advice:	•Paediatric formulation (or other pharmaceutical quality) development questions, questions on the design and conduct of juvenile animal and clinical paediatric (including extrapolation) studies
SAWP/PDCO interaction	•Continuing PDCO involvement in SAWP procedures, 'reverse' involvement of SAWP in PDCO procedures, intended enhancement of PDCO representation in the SAWP

PIP: paediatric investigation plan, PDCO: paediatric committee, SAWP: scientific advice working party

Very first draft scientific advice transformation map

Foreseen changes
EMA development PL for PRIME
Enhanced PRIME Rapporteur support and scientific advice agility
Pilot for parallel scientific advice with MD regulators
Pilot for consolidated pre-CTA/pre-MAA scientific advice process (via ACT-EU)
PRIME development tracker and readiness meeting
‘Reverse’ involvement of SAWP in PDCO procedures
Improvement of EMA scientific advice/development support webpages

PL: product lead, PRIME: priority medicine, MD: medical device, CTA: clinical trial application, MAA: marketing authorisation application, SAWP: scientific advice working party, PDCO: paediatric committee

Status of other industry-proposed changes

Proposed change	Dependencies
Patient-specific Briefing Document section	ICH work on patient-focused drug development
Revised HTA parallel JSC process	HTA legislation implementation
Parallel scientific advice process with NITAGs	Regulatory capacity
Q&As on evolving topics	Working Party re-organisation
Leveraging COVID-19 regulatory flexibilities	Pharma strategy review
Increased involvement of SAGs	Length of scientific advice procedure
Collaboration with academia	Various initiatives
Wider application of enhanced public communication used for COVID-19	Various initiatives
Resourcing of regulatory network	Various initiatives

ICH; international council for harmonisation, HTA: health technology assessment, JSC: joint scientific consultation, NITAGs: national immunization technical advisory groups

Take home messages

Scientific advice delays uncommon, but assessment capacity requires increase

New briefing document template is a welcome simplification; its use becomes mandatory from January 2023

Regulatory interaction on paediatric developments to be handled more via PDCO-operated procedures; the SAWP/PDCO interaction is subject to constant assessment and improvement

Continuous evolution of scientific advice framework monitored via a transformation map

Q&A