Update on latest developments in scientific advice

10th Industry stakeholder platform on research and development support

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Outline

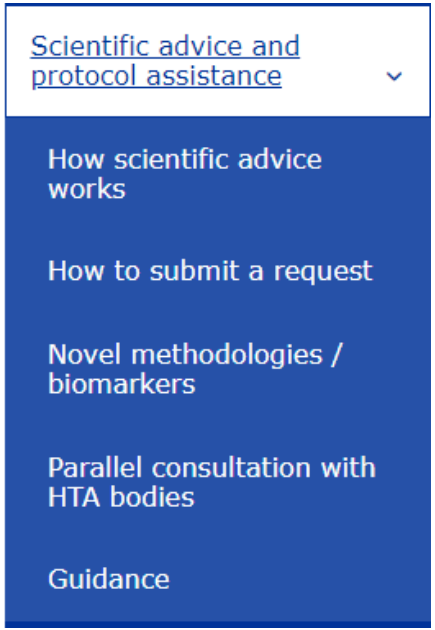
Revision of scientific advice public guidance

Scientific advice volumes and capacity

Initiatives to progress towards integrated scientific advice

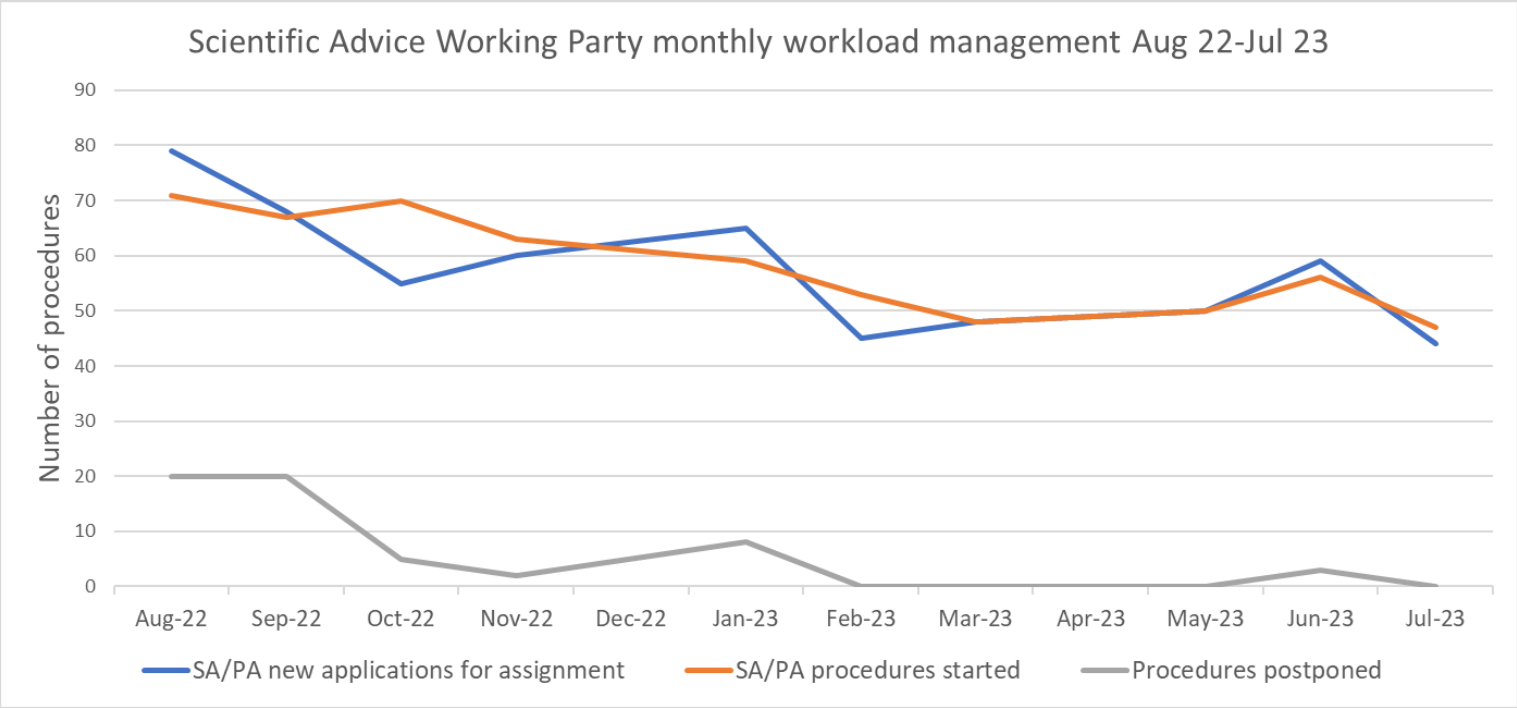
1 10th Industry stakeholder platform on research and development support

Scientific advice public guidance

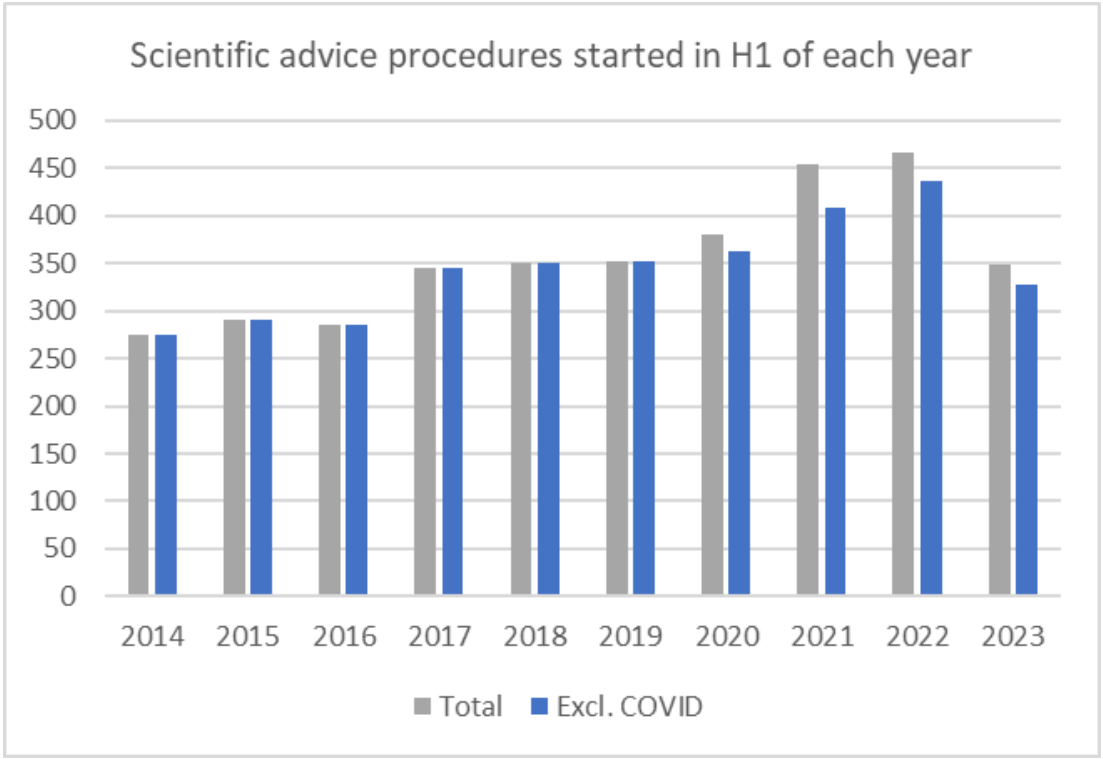


- Re-structuring of information on scientific advice webpages with deletion of obsolete content is in progress
- 'How scientific advice works' and 'Guidance' webpages to be removed
- Most guidance to be found on landing page while technical parts to be concentrated on 'How to submit a request'
- Simplification of access to information
- Further re-structuring of information in scientific advice webpages to follow

Scientific advice capacity



Scientific advice volumes



Updated scientific advice transformation map

Foreseen changes	Status
EMA development PL for PRIME	Reprioritised in light of PRIME pilots
Enhanced PRIME Rapporteur support and scientific advice agility	Expedited SA pilot (agenda p.3)
Options for parallel scientific advice with MD regulators	Expert panel SA, Focus Group (agenda p.8)
Pilot for consolidated pre-CTA/pre-MAA scientific advice process (via ACT-EU)	Reprioritised due to other urgencies (mainly CTR implementation)
PRIME development tracker and submission readiness meeting	Relevant pilots (agenda p.3)
'Reverse' involvement of SAWP in PDCO procedures	In place but has not been used yet
Improvement of knowledge management/institutional memory	EMA IT developments in progress
Improvement of EMA scientific advice/development support webpages	Work in progress
Review of the QoNM framework	Starting in Q3 2023

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

Status of other industry-proposed changes and initiatives

Proposed change	Status/Dependencies
Patient-specific Briefing Document section	Awaiting results of relevant ICH work
Enhanced HTA parallel JSC process	Parallel EMA/HTAb SA, HTAR implementation
Parallel scientific advice process with NITAGs	Impeded due to regulatory capacity constraints
Q&As on evolving topics	First Q&A in drafting stage
Leveraging COVID-19 regulatory flexibilities	Addressed via the pharma legislation revision
Increased involvement of SAGs	Theoretically possible but logistically difficult
Collaboration with academia	Pursued towards addressing network capacity constraints
Wider application of enhanced public communication used for COVID-19	Various proposals being considered as part of the lessons learned from the COVID-19 pandemic
Resourcing of regulatory network	Wider problem, various initiatives ongoing

ICH; international council for harmonisation, HTA: health technology assessment, HTAb: HTA body(ies), HTAR: HTA Regulation (EU) 2021/2282, JSC: joint scientific consultation, NITAGs: national immunization technical advisory groups, SA: scientific advice

Take home messages

Restructuring of scientific advice public guidance will increase user-friendliness

Scientific advice delays resolved

Scientific advice transformation map has been updated with recent developments and continues to act as a monitor of the scientific advice evolution

Thank you!