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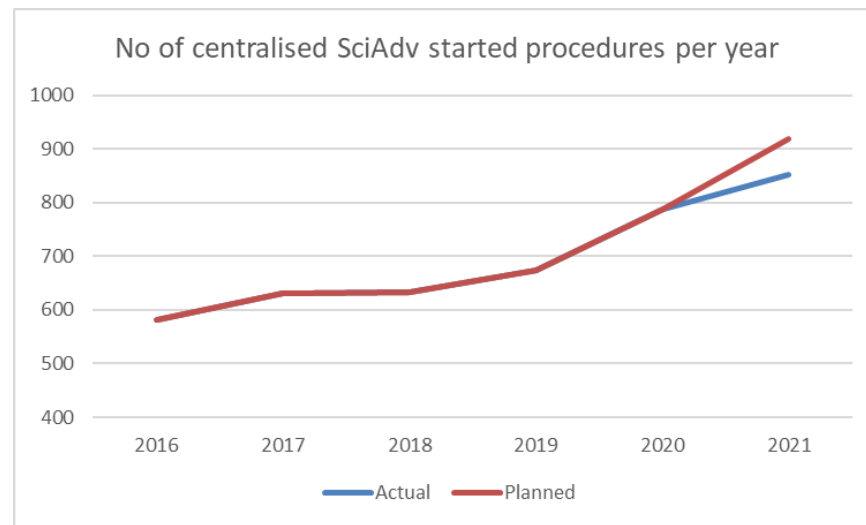
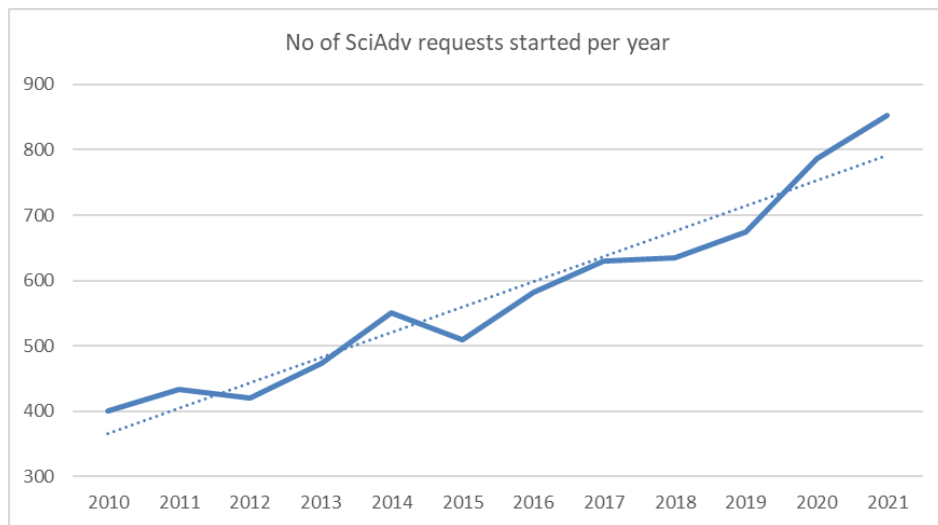
Status update in terms of scientific advice capacity and development of proposals moving forward

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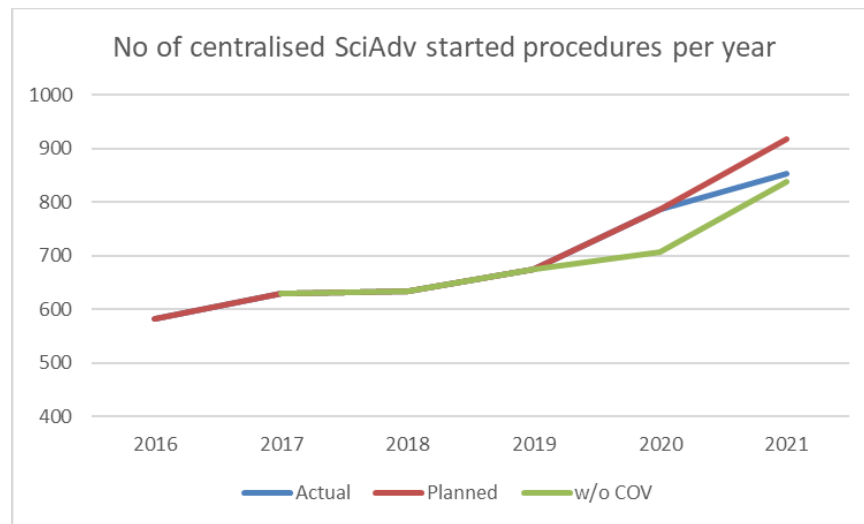
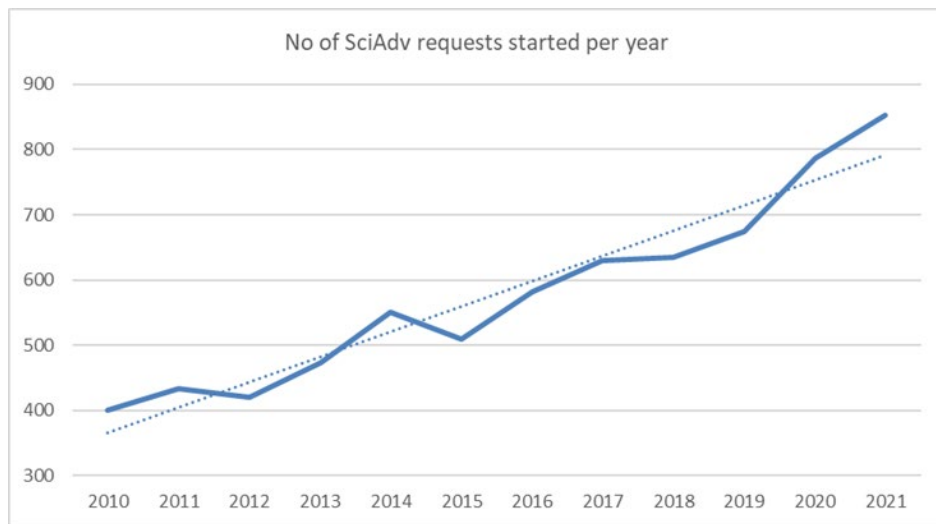
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Increasing SAWP workload is reaching the system capacity



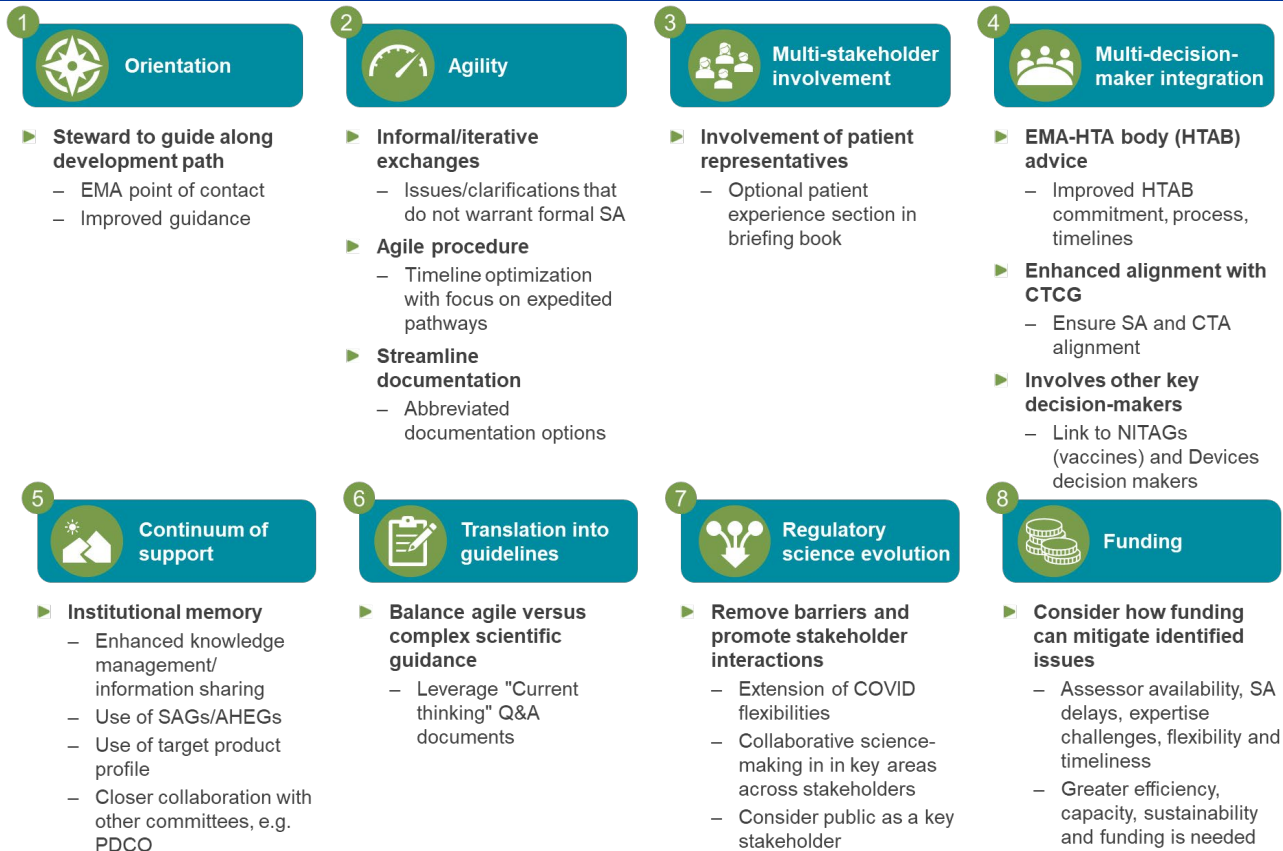
Increasing SAWP workload is reaching the system capacity



Scientific advice capacity: current status

- Following the July 2022 plenary meeting postponements of procedure start are in the single digits
- Adaptations of SAWP membership, more stringent application of validation rules and, more recently, higher flexibility in multinational team formation have helped reduce delays
- Normalisation of submission numbers has played the biggest role in tackling the problem
- Currently, delays focus mainly on paediatric-only developments

The EMA Focus Group on 'practical application of integrated development support' recommendations



SAWP process optimisation workshops recommendations

- improve public guidance to better clarify scope of scientific advice
- unify Briefing Document and First Report templates and mandate Briefing Document template
- increase SAWP capacity, facilitate multinational assessment team formation and adapt expertise to novel needs
- increase time to First Report discussion to engage non-SAWP (e.g. PDCO, CAT etc.) peer reviewers in advance of the discussion
- optimise SAWP plenary time usage
- improve IT tools supporting knowledge-sharing/knowledge management

Ongoing and planned actions

- Improvement of public guidance
 - to clarify scope of scientific advice
 - to guide through various regulatory interaction opportunities
- Update of Briefing Document template to facilitate First Report generation
- Changes to and expansion of SAWP composition with the next member re-nomination exercise
- Alignment with CTCG and rationalisation of scientific advice opportunities in the EU pursued through ACT-EU Priority Action 7
- Stewardship and agility pursued via the PRIME 5-year report follow-up actions (refer to agenda point 6)

Ongoing and planned actions

- For the patient involvement, refer to agenda point 4
- For HTA and med. Dev. decision-maker interactions, refer to agenda points 2C, 5, 8
- For institutional memory/continuum of support
 - AI/analytics tools to improve EMA and network utilisation of EMA sci. adv. repository
 - Continuous discussion to improve interaction with PDCO
 - Improvement of institutional memory via the PRIME development tracker
- Q&A generation to kick-off in the oncology area facilitated by the new working party structure
- Interactions with academia (particularly for ATMPs) and capacity discussions at HMA level

Take home messages

- Numerous EMA and EMRN initiatives are underway to evolve both the scientific advice offering and development support in general
- A more holistic transformation map of the scientific advice (and development support) framework is needed
- Continuous dialogue with all stakeholders is key to ensuring that the adaptation is such that development support will better serve patient and public health needs

Q&A