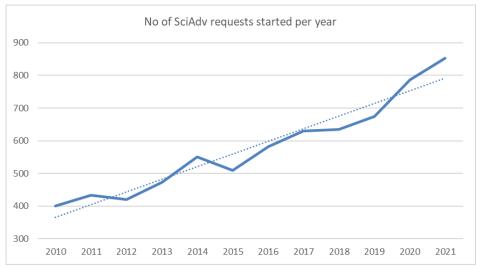
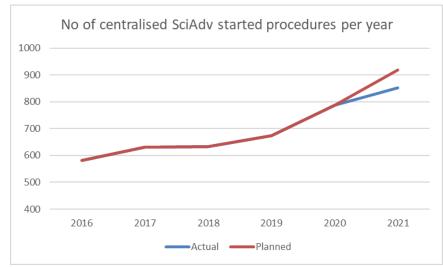


Status update in terms of scientific advice capacity and development of proposals moving forward



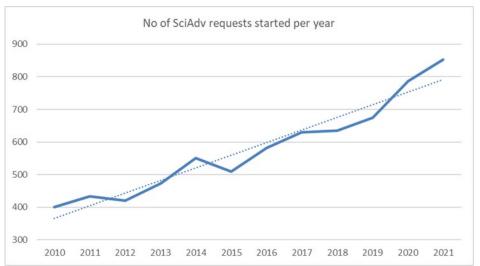
Increasing SAWP workload is reaching the system capacity

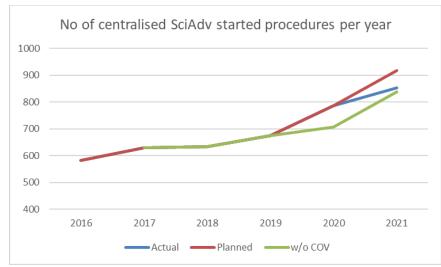






Increasing SAWP workload is reaching the system capacity







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







- EMA point of contact
- Improved guidance



Agility

Informal/iterative exchanges

- Issues/clarifications that do not warrant formal SA
- Agile procedure
 - Timeline optimization with focus on expedited pathways
- Streamline documentation
 - Abbreviated documentation options



Involvement of patient representatives

 Optional patient experience section in briefing book



Multi-decisionmaker integration

EMA-HTA body (HTAB) advice

- Improved HTAB commitment, process. timelines
- Enhanced alignment with **CTCG**
 - Ensure SA and CTA alignment
- Involves other kev decision-makers
 - Link to NITAGs (vaccines) and Devices decision makers



Funding

Remove barriers and promote stakeholder interactions

Regulatory

science evolution

Extension of COVID



Continuum of support

Institutional memory

- Enhanced knowledge management/ information sharing
- Use of SAGs/AHEGs
- Use of target product profile
- Closer collaboration with other committees, e.g. **PDCO**



Translation into quidelines

- Balance agile versus complex scientific quidance
 - Leverage "Current thinking" Q&A documents

- flexibilities
- Collaborative sciencemaking in in key areas across stakeholders
- Consider public as a key stakeholder

Consider how funding can mitigate identified issues

- Assessor availability. SA delays, expertise challenges, flexibility and timeliness
- Greater efficiency. capacity, sustainability and funding is needed

8th Industry stakeholder platform on research and development support

The EMA

'practical

integrated

support'

4

Focus Group on

application of

development

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 renomination 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