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

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Increasing SAWP workload is reaching the system capacity
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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

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<th>Orientation</th>
<th>Agility</th>
<th>Multi-stakeholder involvement</th>
<th>Multi-decision-maker integration</th>
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| - Steward to guide along development path  
  - EMA point of contact  
  - Improved guidance | - Informal/iterative exchanges  
  - Issues/clarifications that do not warrant formal SA | - Involvement of patient representatives  
  - Optional patient experience section in briefing book | - EMA-HTA body (HTAB) advice  
  - Improved HTAB commitment, process, timelines |
| - Agile procedure  
  - Timeline optimization with focus on expedited pathways | - Streamline documentation  
  - Abbreviated documentation options | - | - Enhanced alignment with CTCG  
  - Ensure SA and CTA alignment |

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| - Institutional memory  
  - Enhanced knowledge management/information sharing  
  - Use of SAGs/AHEGs  
  - Use of target product profile  
  - Closer collaboration with other committees, e.g. PDCO | - Balance agile versus complex scientific guidance  
  - Leverage “Current thinking” Q&A documents | - Remove barriers and promote stakeholder interactions  
  - Extension of COVID flexibilities  
  - Collaborative science-making 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 |

4th Industry stakeholder platform on research and development support
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

8th Industry stakeholder platform on research and development support
### 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