Progress so far and summary next steps

Focus Group on agility in scientific advice

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Outline

As discussed at the previous R&D platform meeting, this Focus Group aims to consider the industry proposal for an agile scientific advice process and explore feasibility and conditions for implementing such process.

Deliverables of the Focus Group are:

- Define scope, submission requirements and assessment resource allocation for an agile process
- Define timelines and outcome of the process
- Decide on feasibility of agile process implementation
- (Depending on feasibility) Decide on the conduct of a pilot

Focus group – main discussions

- EMA presentation on SAWP "state of the art" – volumes; resourcing; workflows; fees;
- Industry presentation: value and gaps in current SA offering; needs; initial proposal on how an "agile" SA process could address these;
- Brainstorming on principles that Agile SA's should adhere. Agreed to work on a proposal:

1) Delivering fast/efficient outcomes
2) Of focused scope (identifiable at eligibility/validation stage)
3) Safeguarding the need for EU centralised system representativeness
4) Limited to routine/core drug development topics (i.e. not covering "new" elements/technologies)
5) Workload neutral (intended as balance between process agility/duration and quantity of submission content for review at individual assessor level)

- Agreed to look at "mock" case studies, EMA exploring relevant operational aspects impacted; re-assess plan for delivery after discussion on case studies

Outline of proposal being discussed

Scope

- Agile advices can be intended as "follow-up" (related to a recent SA) request or on a "new" development
- Scope: ideally limited to one discipline (Q/NC/C), where broader internal consultations are generally not needed (TC2 discussion on case studies illustrative of the approach)
- Number of questions limited (1-3); NB - idea is not that multiple agile requests replace a "full" SA
- Encompassing, but not limited to, drug development programmes addressing an UMN

Operations

- Supporting documentation to be concise/limited in volume (as to enable rapid review) for follow-up (i.e., "BD addendum")
- Process de-coupled from regular SAWP-CHMP plenaries; only written exchanges foreseen;
- SAWP maintains option to revert to a "normal" timeline
- Bespoke (tbd) fee to be paid

Next Steps

Discussions to advance:

- Validation aspects (incl. IRIS)
- Assessment team model – for "new" and "follow-up" advices
- Adaptations to the briefing document (and submission package)
- End-to-end process details
- Application of new principles for response drafting
- Brainstorm on KPIs for pilot evaluation

Target

- *iron out details and present at Nov R&D platform meeting*
- *go live Q1 2027*

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Thank you

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