EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Revamping the Scientific Advice process

7th Industry Stakeholder Platform on Research and Development support

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An agency of the European Union

The mandate to change Scientific Advice

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EMA RSS to 2025

- Iterative framework addressing the continuum of evidence generation
  - More flexible/agile SA for PRIME products
- Multi-stakeholder (HTAs, patients, healthcare professionals, payers) engagement
  - Enhanced collaboration with Notified Bodies for medical devices/companion diagnostics
  - Integration with clinical trials approval and GCP oversight
  - Translation of innovation (links with Innovation Task Force and EU Innovation Network)
- Enhance/improve the EMA qualification process
  - For digital endpoints
  - For data qualification purposes

EMRN to 2025

- Improved interactions with HTAs/payers to improve patient access to medicines
- Develop collaboration between various groups involved in scientific advice and regulatory guidance provision
- Coherence between innovation and scientific advice provision
- Consistency and convergence between EMA and national scientific advice
- Foster simultaneous national scientific advice (SNSA)
- Modernisation of scientific advice provision via digitalisation

Scientific advice requests in time

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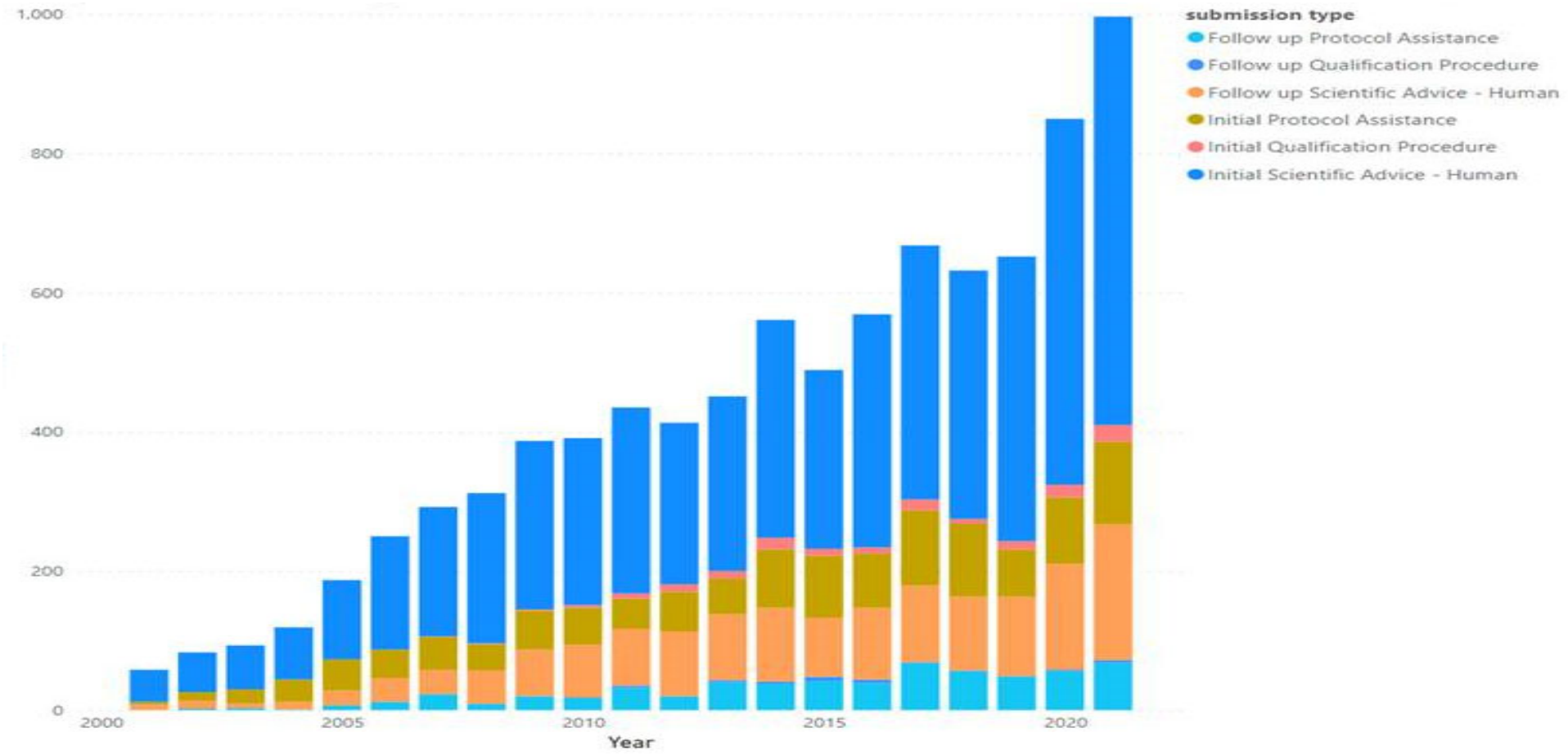

Focus of today's update

- Industry Focus Group on practical implementation of integrated development support
- Ongoing discussions with SAWP on revamping the scientific advice process (precipitated by SAWP capacity constraints)

Industry proposals (summary)

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Under orientation/stewardship

- Development PL
- Product-level Rapporteur(s)
- Optional first orientation meeting
- *Improvement of guidance: interaction tools (formal/informal) summary, SME guide, one-pagers and interactive tools*

Under Agility

- Quick, informal exchanges with PL and product Rap(s)
- Flexible validation/assessment time
- Briefing Doc in ppt format

Under multi-stakeholder involvement

- Special Brief Doc section for patient reps

Under multi-decision-maker integration

- HTA commitment to PCs
- Process and timeline simplification for PCs
- PCs/PSAs to focus on actionable/feasible recommendations
- Link to CTFG/national SA, SNSA
- Link to decision-makers for devices/NITAGs

Industry proposals (summary)

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Under institutional memory/continuum of support

- Knowledge management/info sharing/link to innovation
- Use of SAGs/AHEGs
- Closer collaboration with PDCO
- *Target product profile/product summary*

Under translation into guidance

- Publication of 'current thinking' Q&As or other flexible guidance format

Under regulatory science evolution

- Extension of other (e.g. GMO) COVID flexibilities
- Collaborative science-making across stakeholders (e.g. ATMPs)
- The public as stakeholder/communication

Under funding

- Support by industry in regulatory guidance revision towards higher quality submissions
- Regular industry/EMRN discussion forum
- Industry consultation in SA fee revision

Ongoing discussions with SAWP (some preliminary reflections)

- Improve/clarify guidance on inappropriate or less meaningful SA questions and on submission requirements
- A more seamless transformation of Briefing Document to First and Joint Reports
- Review of procedural time lines (e.g. validation, assessment time and possibility for LoI with written responses, when needed)
- Need for prioritisation criteria to manage delays
- Possibility for some product-level SAWP coordinators

Scientific advice capacity bottlenecks

- Surges in submissions in May, June and September 2021, coupled with network assessor capacity constraints, led to postponement of the start of procedures
- Implications for development plans but also for the assessment due to modifications and, more recently, withdrawals during the procedure
- All therapeutic areas are affected, but anti-infectives and ATMPs with quality area of advice more selectively
- Prioritisation has been attempted based on the stage of the submission, balancing against the SAWP/network variety of expertise type to the extent possible
- Adaptations to SAWP composition from member turn-over aimed to respond to changing needs

What are the short-term measures to address the capacity bottlenecks?

- Strengthened prioritisation of postponed procedures
- Prioritisation for PRIME product scientific advice requests
- Some flexibility to exploit SAWP/NCA capacity fully (target: started procedures to systematically exceed submissions)

- More structural changes and efficiency gains needed for the medium-/long-term

Next steps

- Careful consideration of all proposals and integration into an implementation plan
  - Consultation with industry stakeholders on selected topics
- Low-hanging fruit, e.g.
  - improvement of public guidance/manuals/one-pagers/interactive tools
- Medium-term solutions in the making, e.g.
  - digital tools (IRIS) to increase intra-network linking and knowledge-sharing
  - Q&A publication and cross-committee/WP interactions linked to Working Party re-structuring
  - Multi-decision maker interactions improvement linked to new legislation implementation
- Medium-term solutions requiring careful consideration e.g.
  - Options for enhanced development support oversight

Looking forward to the discussion!