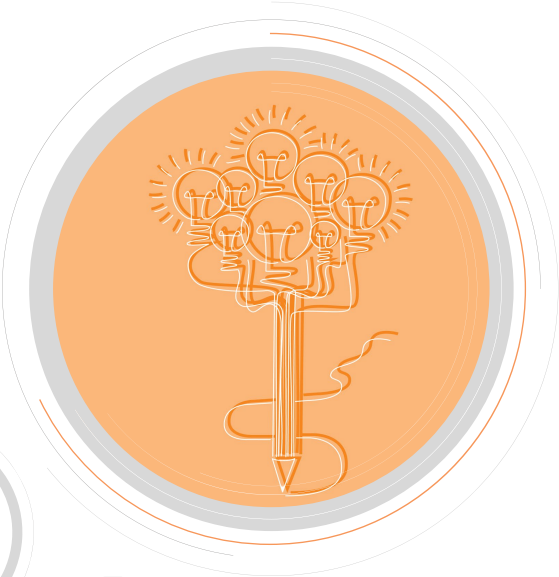
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Diversify and integrate the provision of regulatory advice along the development continuum



Underlying actions

EMA's Regulatory Science Strategy to 2025 – Human Stakeholder Workshop

Chaired by Anja Schiel, SAWP and Koenraad Norga, PDCO on 18 November 2019
Presented by Spiros Vamvakas, Head of Scientific Advice, EMA

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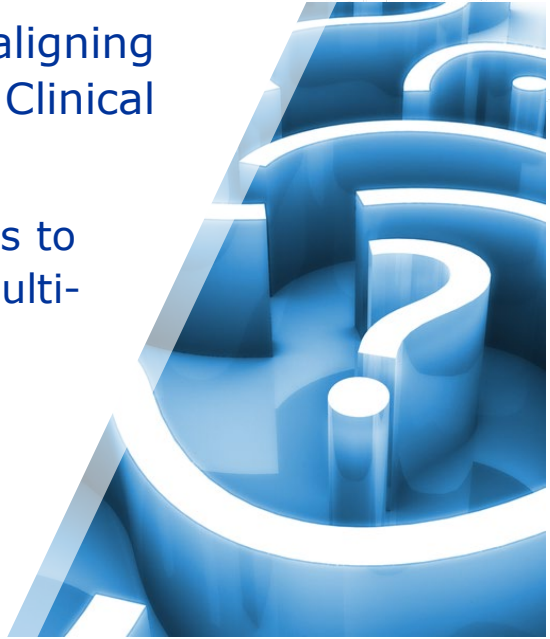
Diversify and integrate the provision of regulatory advice along the development continuum

Promote more integrated medicines development aligning Scientific Advice, Clinical Trials approval and Good Clinical Practice oversight

Create complementary and flexible advice mechanisms to support innovative product development expanding multi-stakeholder consultation platforms

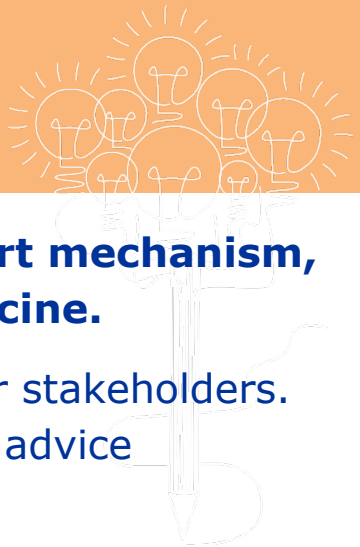
Facilitate translation of innovation via a re-engineered Innovation Task Force and synergy with an evolving EU-Innovation Network platform



Promote more integrated medicines development aligning Scientific Advice, Clinical Trials approval and Good Clinical Practice oversight

- A pilot could be used to better determine how to enhance support in a more holistic fashion for example by aiming for better linkage and dialogue between national CTA approvers and EMA-led scientific advice.
- **Investigate possible IT solutions to facilitate the sharing of scientific advice documentation (briefing materials, meeting outcomes, minutes) easily across the EU regulatory network and with individual companies e.g. via a dedicated, confidential portal. This could be product-specific and would be added to during the lifecycle of the product.**

Create complementary and flexible advice mechanisms to support innovative product development also expanding multi-stakeholder consultation platforms



- **Redesign of a more flexible and integrated R&D product support mechanism, providing agile dynamic advice across the lifecycle of the medicine.**
- Quicker, voluntary, and flexible engagement with regulators and other stakeholders. The developer should have the ability to select from multiple levels of advice engagement based on the attributes of a particular product.

Create complementary and flexible advice mechanisms to support innovative product development also expanding multi-stakeholder consultation platforms

- **Changing pace and process of innovation along the development continuum. This envisaged dynamic advice is also needed to adaptably accommodate specialised input for specific types of products (e.g. paediatrics, drug-device combination products).**
- **Promoting a more interactive approach during the procedure and allowing greater access to specialised working groups when novel approaches are proposed.**
- Bridge the advice and decision-making gap across the EU regulatory system (i.e., EMA, EMA's Committees, National Competent Authorities) and beyond (e.g., US FDA).

Create complementary and flexible advice mechanisms to support innovative product development also expanding multi-stakeholder consultation platforms

- **Provide preliminary feedback ahead of discussion meeting so that the sponsor can also suggest additional topics for discussion based on this feedback. In this way, the developer's discussion topics can be added to those determined by the SAWP/HTA bodies (i.e., a more interactive engagement process between the sponsor and the SAWP).**
- Offer even shorter timelines for follow-up questions (e.g., considering new information or changes to the development programme since the initial advice was given).

Create complementary and flexible advice mechanisms to support innovative product development also expanding multi-stakeholder consultation platforms

- **Tailored stakeholder input for medicine-device combinations: It should be possible to seek timely joint advice on medicine-medical device combination products by involving notified bodies, NCAs and/or EMA, depending on the questions.**
- Taking the learnings from PRIME, national agency experts could provide advice and lead on to be Rapporteurs allowing integration of the advice from clinical trial through approval and throughout the lifecycle.
- Expanding PRIME eligibility based on non-clinical and tolerability data to non-SME/academia would also be helpful.

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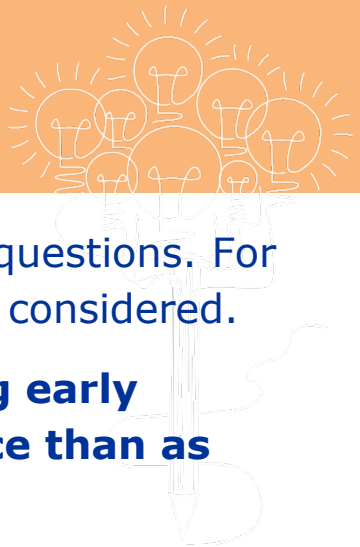


- It should be possible to seek timelier advice on more straightforward questions. For instance, a process similar to Japan PMDA's "Pre-meetings" should be considered.
- **The timing of PIPs could be more flexible and agreed on during early scientific advice such that they become based more on evidence than as currently on speculative assumptions.**

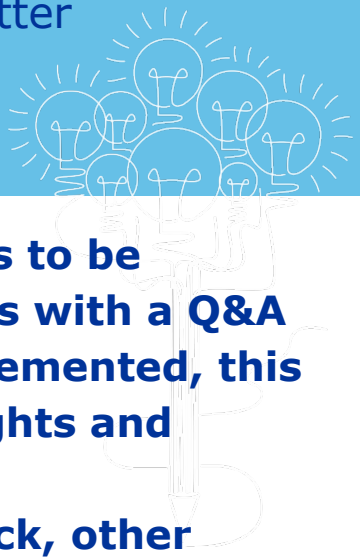
Create complementary and flexible advice mechanisms to support innovative product development also expanding multi-stakeholder consultation platforms

- **For prophylactic vaccines, involvement of recommending bodies (NITAGs) is key and not yet routinely possible (only one pilot so far). Insist on the need to consider vaccine specificities when creating multi-stakeholder consultation platforms.**
- **The details of the pathway should be drafted in collaboration with relevant stakeholders (e.g. through a multi-stakeholder workshop) and tested via a voluntary pilot process.**

Facilitate translation of innovation via a re-engineered Innovation Task Force and synergy with an evolving EU-Innovation Network platform

- The ITF should be integrated into other advice platforms and advice on more general topics or concepts should be afforded.
- **The Innovation Task Force (ITF) could enhance its role and be available for products later in development.**

Facilitate a more iterative engagement framework that allows for better reflection of the continuum of evidence generation and development decision including making new trends and considerations publicly available



- **Consider a more iterative guidance approach: some guidelines to be supplemented by formal adaptive sections of guidance such as with a Q&A section that could evolve with more frequent updates. If implemented, this adaptable section would more quickly communicate new insights and learnings based upon advancing product experiences, academia/investigators' insights, patients'/clinicians' feedback, other regulators' changes, scientific advice results, product qualifications, stakeholder workshops, etc.**

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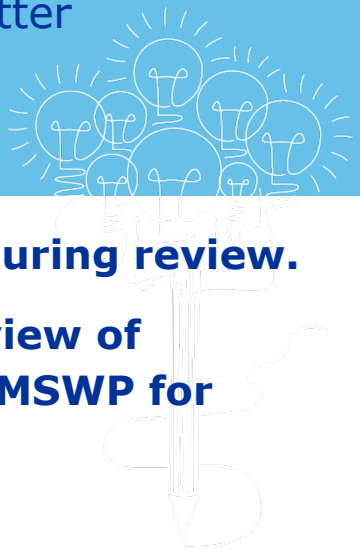

- **Integrate the opportunity for iterative CMC data submission during review.**
- **This proposal can be achieved by delegation of advice and review of dossiers by relevant Working Parties (e.g. BWP for biologics, MSWP for M&S, Biostats WG).**
- Enhanced dialogue with the EU PAT team.
- Consider special perspectives for different types of products (e.g., ATMPs, paediatrics, drug-device combination products).

Any questions?

Further information

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