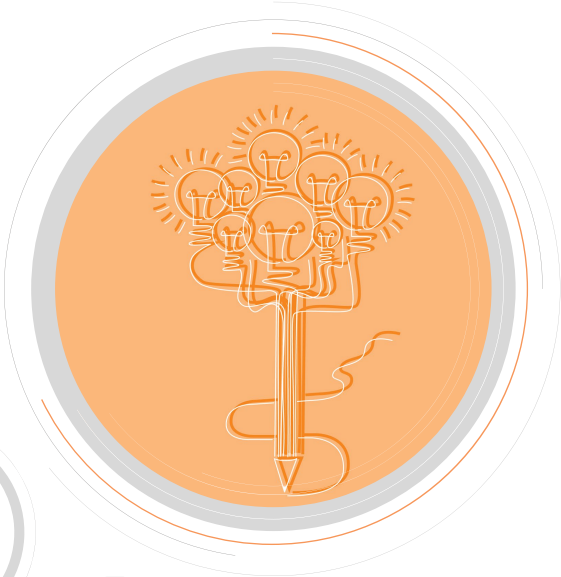
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Developing scientific advice/assessment pathways



Feedback from breakout session 3A

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

Presented by Anja Schiel, SAWP and Koenraad Norga, PDCO on 19 November 2019

Disclaimer

Comments to the underlying actions represent the views of stakeholders and not the European Medicines Agency.

The fact that these comments from stakeholders are displayed in the presentation does not mean we endorse them or commit to fulfil them in any way.

High level actions & feedback – Scientific advice

Call for more interaction:

- Need guidance from early stages and throughout development, following the continuity of evidence generation - reflect on optimal modalities for providing advice
- Problem: many stakeholders who act on their own – opportunity to work together
- Noted that academics may lack awareness about advice opportunities hence a funder should mandate contact with regulators
- Need to reach out to other structures, such as ERNs

High level actions & feedback – Scientific advice

Call for more interaction (cont.):

- Suggestion to introduce undergraduate courses on regulatory science
- Funders should request SA before funding like for Orphan Drugs in the Horizon program a few years ago
- Advice is provided in silos from different stakeholders, better integration is required to avoid divergences

High level actions & feedback – Scientific advice

Engagement platforms:

- Avoid that two European institutions deal with the same questions
- Manage the sharing of knowledge and experience whilst ensuring independence of assessment
- Noting the upcoming piloting of simultaneous multinational SA
- Need to develop a landscape of development support platforms in Europe
- R&D platform: could be enlarged to provide a transformation map

High level actions & feedback – Scientific advice

Engagement platforms (cont.):

- Call for progressing with medical device related scientific advice, as the new player in the multi-stakeholder SA
- Call for ITF for late stage developments: Need for informal discussions with many stakeholders
- Vertical interactions along the development and horizontal interaction among many stakeholders

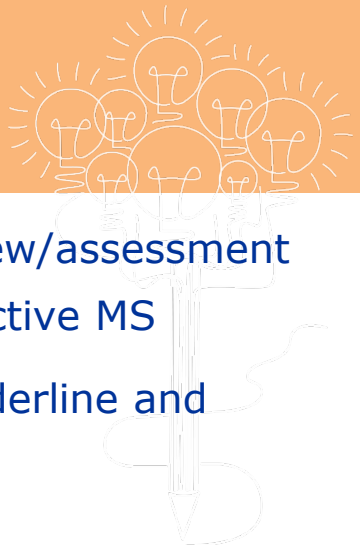
High level actions & feedback – Integrated evaluation pathways

- Much can be resolved with guidance on roles and responsibilities but need joint discussions as responsibilities are spread over different stakeholders as technology is advancing rapidly
- EMA in unique position to engage with different stakeholders to share expertise and competence and act as facilitator
- Recognition to exploring/having interactions (informal and formal) with Notified Body – during scientific advice and assessment
  - NCA can already provide joint regulatory but not scientific advice for device development
  - Legal considerations on what NBs may be able to do in terms of providing advice
  - Considerations to be explored in workshop/pilot

High level actions & feedback – Integrated evaluation pathways

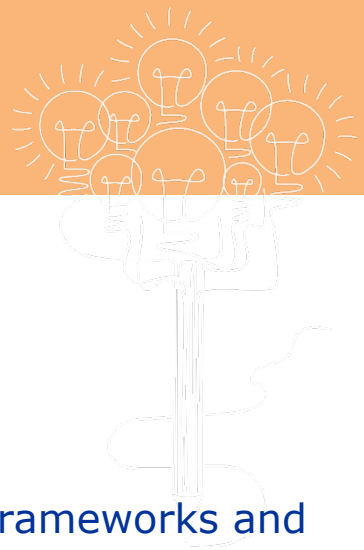
- Create workable solutions within existing regulatory legislation exploring flexibility in existing regulatory system
- Urgency to resolve practical issues – MDR implementation May 2020
- Medical device guidance is developed by experts from MS with the support of expert panels
  - Involve relevant device stakeholders
- Support for informal Workshop with different stakeholders with pilot case studies to familiarise and explore opportunities

High level actions & feedback – Integrated evaluation pathways



- Involvement of EU-IN members with knowledge and expertise in review/assessment of personalised medicine, CDx and MD as expertise available in respective MS
- Importance of reaching consensus/reach common mechanism on borderline and classification – brought to attention of Pharmaceutical Committee
  - Continuous engagement of HMA-CAMD
  - Build on Helsinki procedure – explore EMA as "coordinating body" as remit with NCAs
- Education/understanding at broad level on biomarker validation/best practices
- Better alignment on requirements between device and medicine developers

High level actions & feedback – Integrated evaluation pathways



What should be in place in 2025?

- Easy access to regulatory advice and support
- Fully integrated system (one "platform" / contact point as entry door)
- Holistic understanding and collaboration between the two regulatory frameworks and mechanisms of consultation (procedures) in place
  - EU-wide harmonisation (long term)
- True integration of patients at all levels with access to medicines, not limited by price

Roadmap of actions/deliverables – Integrated evaluation pathways

Regulators

- Enhance communication across stakeholders
- Build network of expertise and training
- Workshop to discuss case studies/examples (e.g. Art 117)
- Explore establishing multi-stakeholder group to establish processes
- Develop relevant procedural and scientific guidance

Stakeholders

- Provide relevant case examples to support WS/discussions
- Support and highlight need for EU-wide harmonisation to EC and NCA
- Provide examples where development has been facilitated in other jurisdictions as circumstances are “better”

Any questions?

Further information

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