Informal Innovation Network
Draft Horizon Scanning Assessment Report

Artificial Intelligence

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Joint HMA/EMA workshop on artificial intelligence in medicines regulation

Disclaimer

- *These findings are preliminary and subject to change*
- *They reflect the outcome of an exercise based on hypothetical case studies*
- *None of the content of the report should be taken as the regulatory thinking or position of the ICMRA members*

Background

- The International Coalition of Medicines Regulatory Authorities (ICMRA) is a strategic, executive-led organisation
- The ICMRA's Informal Network for Innovation seeks to identify challenges and potentially adapt regulatory frameworks to facilitate safe and timely access to innovative medicines.
- As part of this, horizon scanning is being used to identify challenging topics, based on hypothetical case studies, to stress-test regulatory frameworks, anticipate new areas of expertise, and develop recommendations for regulatory authorities to prepare for innovation

Background

- This report details the preliminary results of the horizon-scanning exercise in Artificial Intelligence (AI).
- The working group members are:
  - AIFA, Italy
  - EMA (lead), EU
  - DKMA, Denmark
  - FDA (observer), USA
  - HC, Canada
  - HPRA, Ireland
  - Swissmedic, Switzerland
  - WHO

AI Sub-group
AI and medicines regulation

Two hypothetical case studies were used to stress test the regulatory systems of ICMRA members:

1. **Central Nervous System App using AI:**

diagnose and assess CNS disease status for selection of patients to be included in clinical trials; measure adherence and response to therapies in clinical trials and post-marketing (endpoint, and effectiveness);

2. **AI in pharmacovigilance**:

fulfilling pharmacovigilance obligations via an AI system, screening both literature and signals.

Preliminary Recommendations 1
- AI Sub-group -

Workshop recommendation category	ICMRA Preliminary Recommendation
Develop a framework to assess and validate AI	Validation of AI use would require a level of understandability and regulatory access to the underlying algorithms and datasets; there are limits to validation and predictability as AI can evolve autonomously;
	For AI linked to the benefit/risk (B/R) of a medicinal product, companies should have strengthened governance structures to oversee the evolving algorithm(s);
	Companies would need to inform regulators if AI updates (either imposed, or self learned) affected the B/R
	Post-licensing management may need adapting to manage updates e.g. a risk based approach to updates of digital tools linked to the B/R of a medicinal product.

Preliminary Recommendations 2
- AI Sub-group -

Workshop recommendation category	ICMRA Preliminary Recommendation
International collaboration	Consider an ICMRA working group on AI to share experiences of regulating AI, and best practices for its use within Authorities;
Build a framework that supports the development of guidelines	Regulatory guidelines for AI development and Apps should be agreed.
Address ethical aspects of AI	Bring together or engage with existing ethics networks/committees and AI expert groups to collaborate on ethical issues of AI in medicines development and use;

Next Steps

- The report and recommendations will be agreed by the ICMRA members (strategic level)

- The ICMRA regulatory authorities will be responsible for their approach to implementing them

Any questions?