Global regulators call for international collaboration to integrate real-world evidence into regulatory decision-making.

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EMA has endorsed a joint statement calling for international collaboration to enable the generation and use of real-world evidence for regulatory decision-making published today by the International Coalition of Medicines Regulatory Authorities (ICMRA).

The use of real-world data and real-world evidence in the development, authorisation and monitoring of medicines to support regulatory decision-making is rapidly increasing. Although real-world evidence can play an important role in bridging knowledge gaps, there are still challenges that need to be addressed, such as heterogeneous data sources across the globe and different levels of quality of the data. Interested parties also need to deal with various processes for data sharing and access.

According to a statement published on the EMA website: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19 [1] , international medicines regulators and researchers have worked together to establish or reinforce collaboration allowing efficient sharing of data and experience in relation to real-world evidence. They agreed to further such collaboration beyond the pandemic.

In their statement, ICMRA members pledge to foster global efforts and further enable the integration of real-world evidence into regulatory decision-making. They identify four focus areas for regulatory cooperation:

· harmonisation of terminologies for real-world data and real-world evidence;

· regulatory convergence on real-world data and real-world evidence guidance and best practice;

· readiness to address public health challenges and emerging health threats; and

· transparency.

Global regulators emphasise their commitment to steer the work in these areas which could be taken forward through a variety of existing fora, including the International Conference on Harmonization (ICH), international standardisation bodies and clusters of interested regulators.

The joint statement was developed following an ICMRA workshop on real-world evidence co-organised by EMA, US FDA and Health Canada, held in Amsterdam in June 2022. Participants from more than 40 countries, representing medicines regulatory authorities globally as well as representatives from the World Health Organization (WHO), shared their accomplishments and challenges in generating real-world evidence to support the evaluation of medicines. As a next step, international medicines regulators will discuss concrete actions to implement the above-mentioned four areas of collaboration.

More information available on the website: https://www.ema.europa.eu/en/news/global-regulators-call-international-collaboration-integrate-real-world-evidence-regulatory-decision [2]

Źródłowy URL: https://archiwum.urpl.gov.pl/pl/node/7152

Odnośniki

[1] https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19
[2] https://www.ema.europa.eu/en/news/global-regulators-call-international-collaboration-integrate-real-world-evidence-regulatory-decision