ICMRA SUMMIT 2025

Amsterdam, the Netherlands, 22nd October 2025

Report

The International Coalition of Medicines Regulatory Authorities (ICMRA) held its annual summit on 22nd October 2025. The summit was hosted and organized by the European Medicines Agency (EMA) at its premises in Amsterdam and brought together leading regulators and experts from regulatory authorities around the world and the World Health Organization (WHO). It was the first time that this summit was organized at the premises of the hosting authority.

The summit included 3 sessions, focusing on Communication aspects, reliance among regulators and the use of Artificial Intelligence in regulatory processes. 120 delegates, a record number, participated, representing 40 ICMRA authorities and the WHO, from all the continents of the world.

Session 1 - Regulators as communicators: promoting science and trust

Co-Chairs: Emer Cooke (Executive Director – EMA) / Mojisola Christianah Adeyeye (Director General - NAFDAC)

In an era of rapid information exchange but also growing challenges such as the spread of mis- and disinformation and polarized public debates, the role of regulators as trusted communicators has never been more critical. The session, co-chaired by the European Medicines Agency (EMA) and the Nigerian National Agency for Food and Drug Administration and Control (NAFDAC), explored how regulatory authorities can effectively promote science and reinforce public trust in health systems.

It was opened by a thought-provoking keynote presentation on the Battle for Trust in Health and Science and the Vital Role of Communications, by Carolyn Paul, from the company Edelman, which has published a series of reports based on original global research in the last 26 years. She presented at this meeting data from the 2025 Edelman Trust Barometer: Special Report on Trust and Health. The data presented showed clearly how trust in the information provided by health authorities has been eroded in the last years, in particular following the COVID-19 pandemic, and how personal communication, such as from friends and families, as well as family doctors, is now often more trusted than official bodies.

After the keynote speech, regulators from around the world presented on current and innovative strategies to communicate with the general public and health-care professionals, how to address mis- and dis-information and how communication has changed in the last 5 years, in particular as a result of the COVID-19 pandemic.

Pamela Aung-Thin, from Health Canada, discussed the regulators' role in promoting science and trust among health-care professionals and how this will be shaped in the future, in the Canadian context. She showed the benefits of a dynamic network which includes actors from the federal government, provincial and territorial governments, indigenous partners and international partners, as well as stakeholders such as health-care professionals, the pharmaceutical industry and consumers groups. The aim is, among other things, to fight mis- and dis-information reaching all regions and cultural backgrounds in a coordinated way, avoiding conflicting or confusing messages.

Mojisola Christianah Adeyeye from NAFDAC (Nigeria), showed the many initiatives NAFDAC put in place to communicate with the general public, highlighting as, also in this case, differentiation of messages across different audiences such as patients, youth, local communities etc. is fundamental to success, as well as using a variety of tailored communication methods, including press, radio, TV, social media, tailored workshops, webinars etc. She also showed the importance of feedback and of measuring the outcome of communication activities, e.g. through media monitoring and surveys. The use of AI and further training of staff, to help them communicate better, are future activities to be pursued.

Patrick Maison, from ANSM (France), showed how the communication strategies to fight mis- and dis-information have changed based on the experiences with the COVID-19 pandemic and other health concerns in France, putting together a wide array of competencies, including social sciences, and in collaboration with patient organisations, health professionals and scientific organisations. Analysis showed that public debate is dominated nowadays by growing scepticism, individual opinions and political instrumentalization, distrust however is more against public institutions than science itself. Possible solutions include recognising that good communication is part of science responsibilities, reinforcing the scientific voice in public debate and using social science to analyse how the public perceives decisions related to health taken by public institutions.

The last presentation from Ton de Boer from MEB (the Netherlands), showed the efforts made by MEB in adapting communication activities to a rapidly changing environment. This includes use of a clear and understandable language to the public, going from text-based messages towards more visual and user-friendly communication, the efficient use of a variety communication tools and channels, use of social media, increased transparency and collaboration with stakeholders.

The main points agreed by the participants at the discussion that followed the presentations were that the use of new, non-traditional approaches to regulatory communication is needed to improve the role of regulators as a trusted source of science-based information and to fight mis- and dis-information, examples included the use of content creators and social media. It is also fundamental to invest in training of existing staff in communication and hiring communicators with specific profiles (e.g. experts in non-traditional approaches to communication) in regulatory agencies.

The development of an ICMRA statement reinforcing the message that regulators need to find innovative ways to communicate better to reinforce public trust and science-based decisions was also supported. International regulatory authorities will share real-world examples of how they engage with the public and key stakeholders through the existing ICMRA communication group, highlighting innovative approaches and success stories from their respective regions. The same group will also host a structured discussion, focusing on lessons learned, best practices, and the evolving responsibilities of ICMRA and international regulators in a complex global landscape.

Session 2 - Global reliance pathways: promoting cooperation and work-sharing

Co-Chairs: Yasuhiro Fujiwara (Chief Executive - PMDA) / Tony Lawler (Head of Agency - TGA)

The practice of 'Reliance' by medicines regulatory authorities is widely accepted and is often an important mechanism used by regulators, irrespective of their maturity level, to support robust regulatory decisions, avoiding duplication of work and optimizing the use of resources. The desire to implement reliance activities in practice is universal across ICMRA members, and many participating authorities use reliance as a cornerstone feature of their regulatory systems. There are, however, shared challenges that hinder the maximum potential of these pathways.

The session, co-chaired by the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) and the Therapeutic Goods Administration of Australia (TGA) was designed to facilitate discussions around ICMRA's role in helping regulators and stakeholders to better understand current practices and initiatives to maximize reliance implementation and the related challenges. The session emphasized the importance of regulatory reliance as a mechanism for cooperation among medicines regulatory authorities and highlighted the need to address barriers to effective reliance, such as trust, information access, and the role of the pharmaceutical industry. The role of ICMRA in influencing key aspects of reliance initiatives globally was also explored.

Hiiti Sillo, from the World Health Organization (WHO), opened the series of lectures with a presentation on the global status of national regulatory systems, highlighting the importance of reliance to support countries with evolving national regulatory systems. He showed success stories of reliance in marketing authorisation, NRA lot release and clinical trials and lessons from GBT assessments, showing the need to reinforce implementation of policies, procedures and legal provisions allowing an effective implementation of reliance procedures. Challenges however remain, including limited regulatory capacity in many countries to regulate through reliance, the need to institutionalise reliance as tool for efficient decision making for initial marketing authorisation and post-approval changes and, very important, access to credible information. The presentation concluded with recommendations for better information sharing among regulators, including verification of sameness, capacity building activities in regulating through reliance, a call to participation in reliance programs and a question to develop practical "how to rely" guidance and tools.

After WHO, regulators from around the world presented their reliance success stories and the challenges encountered.

Ali Ghamrawy from EDA (Egypt) showed how, facilitated by the recognition of EDA as the first African NRA to achieve WHO Maturity Level 3 for both Medicines and Vaccines, an advanced framework for reliance has been established, rooted in the Egyptian legislation, which includes e.g. a Technical Committee which maintains a list of reference authorities and guidelines explaining criteria, requirements and procedures for reliance pathways across the product lifecycle. EDA also joined in 2025 an eight-party MoU between African NRAs recognized at WHO Maturity Level 3 which includes Egypt, Nigeria, South Africa, Ghana, Tanzania, Zimbabwe, Rwanda and Senegal. Among the challenges, limited access to information, divergence of technical formats, sameness of products and insufficient digital infrastructure were mentioned.

Matthew Spencer from Medsafe (New Zealand) illustrated 2 pathways in New Zealand: an Abridged pathway, which envisages half time for review than the standard process (75 days instead of 150), incentivized through lower fees and used consistently by applicants (50% of applications use this pathway) and a Recognition Pathway, designed to improve access to medicines and with approval time of only 30 days (if a medicine is approved by two trusted regulators, Medsafe must approve it through this pathway). The main challenges encountered were the need to change the legislation to introduce pathways like these, communication (internal,

with the general public, health-care professionals and industry) and the establishment of eligibility criteria.

Eveline Trachsel from Swissmedic showed with 3 examples how their agency employs a spectrum of reliance modalities, including mutual reliance with other agencies and supporting other countries through its decisions. Swissmedic can, according to the Swiss legislation, rely on decisions made by other regulators, increasing the number of approved drugs by shortening the time for approval. At the same time, through participation to the Access Consortium, Swissmedic and other Agencies rely on each other. Other authorities then rely on the work carried out by Swissmedic through reliance pathways such as the procedure for the approval of 'global health products' (MAGHP).

The last session presentation was given by Janis Bernat, from the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), who gave the global Pharmaceutical Industry perspective on the opportunities offered by reliance and its challenges. Among the success stories, the ICMRA PQKM project has shown how simultaneous assessments involving more than one NRA are possible, the recognition e.g. of inspection results shows strong progress and the value of reliance is now well understood by regulators and industry alike. As regards the challenges, from the industry perspective the main ones remaining are country-specific requirements and practices, lack of clear guidance for industry and lack of predictability of the reliance processes. The last one in particular can lead to standard processes being perceived as more predictable. As A possible solution, a global forum for sharing best practices was proposed, as well as a workshop on how to conduct reliance-based reviews.

During the discussion that followed, regulators agreed that reliance is a complex but valuable tool for leveraging global expertise, reducing submission gaps and increasing the availability of medicines, while financially saving and using resources more strategically. ICMRA has the possibility to influence key aspects of regulators work and provide strong, inclusive and impactful support. It would be logical for ICMRA to be more involved in providing strategic guidance, support, and directions to help strengthen and expand reliance initiatives globally. While reliance is supported by regulators globally, and there were many successful stories reported, several challenges that need to be overcome were discussed, including the need for easier exchange among regulators of information currently considered commercially confidential, insufficient digital infrastructure (including divergence of technical formats) and language barriers. It is also necessary to understand better the various existing pathways and possibly rationalize them. Industry needs to be part of the discussion to solve these challenges, in particular as regards easier exchange of commercially confidential information among regulators. IFPMA participation to the session was important to move this dialogue forward.

Possible outcomes from this session were to support WHO in the development of "how to rely" guidance/tools, the creation at ICMRA of a forum for exchange of reliance best practices and the start of dialogue with industry on reliance topics, including improved possibilities for exchanging information considered commercially confidential.

Session 3 - Artificial Intelligence in regulatory practices: looking into the future

Co-Chairs: Hisham Aljadhey (Chief Executive Officer - SFDA) / Lawrence Tallon (Chief Executive Officer - MHRA)

As Artificial Intelligence (AI) continues to reshape the landscape of healthcare and drug development, regulatory authorities are increasingly called upon to navigate its opportunities and challenges. The session explored the evolving role of AI in regulatory decision-making and

oversight and aimed to foster dialogue on how ICMRA and its members can support the development of robust, ethical, and future-ready AI practices in regulation.

Co-chaired by the UK Medicines and Healthcare products Regulatory Agency (MHRA) and the Saudi Food and Drug Authority (SFDA), the session featured 2 parts, on emerging principles for the responsible use of AI in drug development and insights into how AI is being integrated into regulatory workflows.

The first presentation, given jointly by Luis Pinheiro (EMA) and Khair ElZarrad (US-FDA), illustrated how EMA and FDA were developing together guiding principles for good AI practice in drug development. The 10 guiding principles are intended to lay the foundation for developing good practice that addresses the unique nature of these technologies and will help cultivate future growth for AI use in the medicine lifecycle. It was recognized that EMA and FDA working together in this field would promote innovation and regulatory certainty, while increasing efficiency, as it is easier to converge early than to try to align after major regulatory authorities issue different standards. The principles developed by EMA and FDA could also be an initial step for broader discussion on future global ethical and regulatory standards on AI.

The next remarks came from Ricardo Baptista Leite, CEO of HealthAI, a Geneva-based non-profit organization which promotes responsible use of AI globally, which includes several ICMRA participating authorities as members. The speech clearly highlighted that AI is here now, and it is here to stay; regulators need to adapt and refocus their work. AI has a huge potential to improve efficiency of regulatory processes and to bring beneficial effects on public health globally, but regulators need to trust these new technologies, as do HCP's and citizens-at-large, while ensuring that they are used ethically and responsibly. Challenges to be overcome include different national and regional requirements, the fast evolving of AI which needs similarly fast regulatory responses, ensuring protection of data security and privacy, ensuring the safety and effectiveness of AI devices used in healthcare and lack of models for pricing and reimbursement of therapies involving AI. To address this challenge, HealthAI has put together a global regulatory network which already includes several official governmental members, namely regulators from the United Kingdom, Singapore, India, Indonesia, Vietnam, Zambia, Brazil, Peru (with more expected to join in 2026).

3 presentations followed, from international regulators from 3 different continents, Africa, Europe and America.

Boitumelo Semete-Makokotlela from SAHPRA (South Africa) showed how AI is already used at SAHPRA to verify automatically parameters at submission such as the type of application, to check if all documents are present in the right format etc. and to prepare an initial technical report and query letter, all preserving privacy and confidentiality by running on a private cloud. The reported accuracy of the tool was high, and a reduction of 75-85% of the time spent on compliance checks was estimated. Several other AI tools will be implemented in the period 2026-2030, which e.g. propose risk-benefit factors and carry out an initial GMP compliance screening, supporting the initial review of submissions.

The presentation from Joaquim Berenguer Jornet (EMA) focussed on how EMA is using AI to improve efficiency and data insights, structuring its work through 4 main pillars: guidelines and policies, tools and technologies, collaboration/change management and experimentation. Use cases received from all the European Union regulatory agencies were collected and assessed, with a view of a phased implementation of the most promising.

The last presentation from Khair ElZarrad (US-FDA) focused on how FDA is striving to provide responsive regulatory input in a very rapidly evolving environment, through a risk-based,

multidisciplinary approach. He highlighted how FDA is in the process of upskilling the available resources, and it is making an effort to harmonise with global partners.

Other authorities in the session panel, such as EDA (Egypt) and Swissmedic, described a range of on-going activities at their agencies involving AI, and it was abundantly clear that there is a lot of experimentation going on around AI among the ICMRA community.

The discussion that followed focussed on common challenges faced by regulators, such as data quality, algorithmic transparency, and cross-border harmonisation, and how international collaboration can help address these issues. The main take-home-message was that, as previously stated by the HealthAI representative, AI is here to stay and will have a huge impact on the work of regulators, as it is both a catalyst and a tool which has the potential to enable more efficiency and data driven decisions. As a result, regulators need to think and work differently. Trust in new technologies however always needs time, and AI is no exception. Innovation will move at the speed of trust. Working together on AI, even more than in other areas, is extremely important for global regulators.

As regards potential outcomes from the session, in addition to ICMRA to continue to be a forum for exchange of information and best practices, it should start working towards globally agreed principles, on how AI should be used ethically in the regulation of medicines. Start of dialogue with HealthAI should also be explored, and a reflection should start on how medicines regulatory authorities can best engage with this initiative.