ICMRA holds high-level meeting on evolving global science and regulatory challenges, hosted by AIFA

The International Coalition of Medicines Regulatory Authorities (ICMRA), a group of leading medicines regulatory authorities and experts from around the world, convened for a three-day meeting to discuss current and emerging challenges in science and global human medicine regulations. The annual ICMRA summit themed "*Evolving science and regulatory challenges*" was held in Rome, Italy, from 28 to 30 October 2019 and was hosted by the Italian Medicines Agency (AIFA).

"*ICMRA reinforces global resilience and protects public health by interacting with leaders from regulatory agencies at international level and by identifying areas for potential synergies,"* said Luca Li Bassi, AIFA Director General. "*We leverage existing efforts to maximize the global regulatory impact."*

Delegates from 28 different countries, representing more than 35 medicines regulatory authorities globally, as well as experts from the World Health Organization, the European Commission and the European Medicines Agency (EMA) engaged in productive discussions about medicines advances and regulation. How to build global reliance among regulators was the *leitmotiv* of this year's summit. Many sessions were dedicated to sharing knowledge, experiences, lessons learned, and outcomes of actions undertaken to promote global cooperation and networking to better tackle common and global issues such as shortages and medicines availability, risk management, transparency.

"The rapidly changing scientific and technological environment is a challenge and an inspiration for us as regulatory authorities from across the world to shape the future of our strategic collaboration and develop common policies that bridge different national legislative frameworks and help us to use our resources and expertise most wisely." said Guido Rasi, ICMRA Chair and Executive Director of the European Medicines Agency (EMA). *"Building global reliance is one of the tools we are exploring to increase availability and accessibility of safe, efficient and high-quality medicinal products for patients worldwide."*

There was a general consensus that a robust consolidated global regulatory system is key for a common approach to major transformation in science and medicine. Digitalized healthcare and innovative designs of patient-centered clinical trials were some of the most important topics discussed during the second day of the meeting. In parallel, with presentations on different national experiences, regulators discussed how to collect and analyse big data and real world evidence to identify and seize upon potential opportunities for the use of innovative sources of data, as well as novel digital health devices and wearables.

Patient-centered and personalized medicine has also been widely discussed by the Heads of Agencies in a panel, because regenerative and advanced therapies represent revolutionary new source of highly personalized treatments with implications on health planning as well as legal and ethical aspects.

Varied experiences have been shared on the increased medical use of cannabis and the related regulatory level of evidence needed to secure safe, and appropriate access to cannabis derivatives as medicines.

Looking ahead

The ICMRA members also discussed the future strategic goals that can be achieved through the coalition: shortage prevention, strengthening of pharmacovigilance systems, supply chain integrity, promotion of biosimilars and of the responsible use of antibiotics to combat antimicrobial resistance were among the priorities debated in the last day of the ICMRA plenary.

As a unique global coalition ICMRA will continue to support international information sharing and crisis response and help to address current and emerging global human medicine regulatory and safety challenges in a transparent and authoritative manner.