ICMRA SUMMIT 2024
Brasília, Brazil, 12 November 2024

Summit opening Remarks

The International Coalition of Medicines Regulatory Authorities (ICMRA) Chair, Ms. Emer Cooke, of the European Medicines Agency (EMA), officially opened with a warm welcome to all participants. Special thanks were extended to the Brazilian Health Regulatory Agency (Anvisa) for hosting the event, coinciding with celebration of Anvisa's 25th anniversary. The forum was highlighted as a vital platform for international regulators to collaborate on strategic solutions in public health, and to consider the rapidly evolving landscape of medicine regulation, driven by ongoing health threats and emerging technologies.

Mr. Antonio Barra Torres, the Vice Chair ICMRA and host of the Summit**,** acknowledged the presence of distinguished representatives from World Health Organization (WHO), Pan-American Health Organization (PAHO), and other global regulatory authorities. He reflected on the challenges posed by global crises, including pandemics, wars and climate change, and their impact on healthcare systems.

Session 1 - COVID-19 Pandemic: Lessons Learned and Future Preparedness for the Next Global Health Emergency

Co-Chairs: Mr. Antonio Barra Torres, MD – President-Director of ANVISA and Dr. Theresa Mullin - Associate Center Director, Center for Drug Evaluation and Research of United States-Food and Drug Association (US FDA)

The Session had two keynote Speakers- Dr. Jarbas Barbosa, Director of PAHO/WHO and Ms. Emer Cooke, Executive Director of EMA and ICMRA Chair, and 2 presentations- Future Preparedness – How pandemic experiences informed the direction and need for recent International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) harmonized guidelines by Mr. Naoyuki Yasuda – Associate Executive Director of Pharmaceuticals and Medical Devices Agency (PMDA) and ICMRA Pharmaceutical Quality Knowledge Management (PQKM) Project – Enabling collaboration and reliance in the oversight of pharmaceutical quality management –to improve regulatory and industry agility and resilience in dealing with medicine supply disruptions by Dr. Lorraine Nolan – CEO of Health Products Regulatory Authority (HPRA).

First Keynote Speaker:

Dr. Jarbas Barbosa, underscored the pivotal role of PAHO in strengthening regulatory frameworks and public health responses across the Americas. He highlighted Brazil's achievement in certifying measles elimination and reflected on the lessons learned from the COVID-19 pandemic, emphasizing the need to enhance national and regional regulatory capacities. Noting disparities in regulatory systems across countries, he detailed PAHO's initiatives, such as weekly meetings during the pandemic, to support less-developed national authorities and promote collaboration. Dr. Barbosa also addressed critical challenges, including

supply chain disruptions and regulatory gaps that hinder access to vaccines and medical supplies, stressing the importance of preparedness and stronger immunization programs.

He further emphasized the necessity of global collaboration, with entities like WHO, World Trade Organization (WTO), and regional regulatory networks playing key roles in knowledge-sharing and technical support. Highlighting the acceleration of emergency regulatory measures, such as Emergency Use Authorization, he pointed to the need for clearer communication strategies to counter misinformation. Dr. Barbosa called for strengthened regional production capacities for medicines and vaccines, advocating for improved pharmacovigilance and surveillance systems. He also discussed the socioeconomic challenges affecting public health measures in Latin America and stressed the importance of equitable vaccine access, warning against the risks of fragmented global cooperation. Concluding his remarks, he urged regulators to repurpose pandemic-era working groups for future preparedness, enhance transparency, and continue fostering international solidarity in public health initiatives.

Second Keynote Speaker

Ms. Emer Cooke, highlighted key regulatory lessons from the COVID-19 pandemic, emphasizing the critical role of global collaboration in public health. She reflected on the rapid mobilization of scientific and regulatory efforts, noting that the pandemic transformed international cooperation from an aspiration into a necessity. Ms. Cooke underscored the fundamental responsibility of medicine regulators in ensuring public trust and safety, particularly when dealing with uncertain and evolving scientific data. She credited EMA's preparedness strategies for enabling swift responses, including managing medicine shortages and accelerating vaccine approvals, while maintaining rigorous safety and efficacy standards.

Ms. Cooke also discussed regulatory innovations introduced during the crisis, such as rolling reviews, hybrid inspections, and enhanced pharmacovigilance measures, which contributed to the timely approval of COVID-19 vaccines. She stressed the importance of clear and consistent public messaging to counter misinformation and strengthen vaccine confidence. Looking ahead, she emphasized the need for sustained pandemic preparedness, improvements in clinical trial frameworks, and stronger communication strategies to address vaccine hesitancy. Concluding her remarks, she cautioned that future global health crises are inevitable and urged regulators to build on the lessons learned to enhance efficiency, transparency, and public trust in regulatory processes.

First Presentation

Mr. Naoyuki Yasuda emphasized the importance of harmonized guidelines in strengthening global preparedness for future public health emergencies. Drawing from the lessons of the COVID-19 pandemic, he highlighted key regulatory challenges, including the impact on clinical trials, the identification of critical endpoints for therapeutic studies, and the ongoing need to assess vaccine safety, particularly for pregnant and lactating individuals. Mr. Yasuda detailed the development of regulatory guidelines, noting the endorsement of a reflection paper in 2022 and its subsequent approval by global regulatory authorities as a significant milestone in advancing regulatory preparedness.

He further elaborated on the role of ICH in modernizing clinical trial methodologies, particularly through updates to Good Clinical Practice (GCP) standards that incorporate

decentralized trials and digital health technologies. Mr. Yasuda introduced the E21 ICH guideline, which promotes the inclusion of pregnant and breastfeeding individuals in clinical research, addressing a critical gap in past studies. He stressed that harmonized regulatory approaches are crucial for ensuring effective responses to future health crises and enhancing industry adaptability. Concluding his remarks, he emphasized that these initiatives are fundamental to proceed interconnection, contributing collectively to a more resilient and globally coordinated public health system.

Second Presentation

Dr. Lorraine Nolan highlighted the critical role of PQKM project and how lessons from the pandemic have enhanced regulatory agility and resilience in medicine supply chains. She traced the origins of this initiative to 2019, initiated by a proposal from the US FDA to foster global regulatory collaboration on post-approval quality changes. Key points discussed included the potential for a unified submission and assessment process among multiple regulatory authorities, the benefits of collaborative regulatory processes in addressing manufacturing changes and supply disruptions, and the significance of the Collaborative Hybrid Inspection and Pilot (CHIP) program. Additionally, Dr. Nolan emphasized the need to develop digital and data infrastructures to enhance regulatory cooperation.

The long-term goal of the initiative is to establish PQKM system, supported by international regulatory bodies such as ICMRA, ICH, Pharmaceutical Inspection Cooperation Scheme (PIC/S), and the International Pharmaceutical Regulators Programme (IPRP). This effort aims to create a structured and harmonized approach to quality data management, strengthening regulatory and industry responses to crises. Dr. Nolan stressed that this initiative extends beyond public health emergencies, as geopolitical and climate-related disruptions increasingly impact pharmaceutical supply chains. By fostering global, inclusive solutions for regulators and industry players of all sizes, the project seeks to ensure medicine availability and supply chain resilience in an ever-changing global landscape.

Key considerations for ICMRA

The session underscored the importance of global regulatory collaboration in strengthening crisis preparedness and response. Key discussions highlighted the need for proactive trust-building in regulatory systems before crises occur, emphasizing investments in pharmacovigilance, multilingual communication strategies, and tackling substandard and falsified products. Participants stressed that harmonizing regulatory requirements remains a significant challenge, with delays in accessing critical health products due to inconsistencies across jurisdictions. The adoption of a unified global dossier approach and optimized regulatory processes, including parallel reviews and enhanced post-market surveillance, were identified as essential strategies for improving efficiency and maintaining public confidence.

Science-based decision-making and transparent public communication emerged as critical factors in maintaining trust, particularly in addressing vaccine hesitancy and misinformation. The erosion of public trust during the pandemic was linked to shifting public health messages, political influences, and misinformation, underscoring the need for proactive public education. Engagement with community leaders, including non-scientific and vulnerable groups, was recognized as a crucial step toward inclusive communication. Resource constraints post-pandemic pose additional challenges, making efficient regulatory practices vital. The session

concluded with a strong call for sustained global collaboration, improved crisis communication, and regulatory agility to navigate future health emergencies effectively.

Session 2 - Beyond Accelerated Pathways: Expanding Regulatory Strategies to Improve Patient Access to Essential Medicines

Co-Chairs: Dr. Yasuhiro Fujiwara – Chief Executive of PMDA and Prof. Hisham S. Aljadhey – Chief Executive Officer (CEO) of Saudi Food and Drug Authority (SFDA).

The session, co-chaired by Dr. Fujiwara and Prof. Aljadhey, focused on expanding regulatory strategies to improve patient access to essential medicines beyond accelerated approval pathways. Prof. Aljadhey emphasized the importance of universal health coverage and the Sustainable Development Goals (SDGs) in ensuring equitable access to safe, effective, high-quality, and affordable medicines. Despite the successes of expedited approvals during the COVID-19 pandemic, challenges persist, with approximately 2 billion people still lacking essential medicines. Key aspects of accessibility—acceptability, availability, and affordability—were highlighted as critical components for ensuring medicines reach those in need.

Dr. Fujiwara reinforced the global significance of ensuring medicine and vaccine accessibility, pointing out that many approved medicines do not reach patients due to structural complexities in national markets. Dr. Fujiwara introduced the session's central theme, regulatory efforts to enhance medicine availability through international collaboration, drawing on lessons learned from past experiences. Key topics included balancing safety and efficacy in accelerated approvals, ensuring that approved medicines are effectively marketed, and addressing financial barriers to access.

This session had 4 keynote speeches from Prof. Tony Lawler, Deputy Secretary, Health Product Regulation Group from Therapeutic Goods Administration (TGA), Australia; Mr. Daisuke Koga, Director of International Regulatory Affairs, Ministry of Health, Labour and Welfare, Japan (MHLW); Dr. June Raine, CEO of the Medicines and Healthcare products Regulatory Agency (MHRA) and Dr. Daniela Marreco Cerqueira, Executive Secretary of the Medicines Market Regulation Chamber, Brazil.

First keynote Speaker

Professor Lawler provided an overview of the TGA's Provisional Registration Pathway, which is comparable to the FDA's Accelerated Approval and EMA's Conditional Marketing Authorization. Established prior to the COVID-19 pandemic, this pathway facilitated the expedited approval of vaccines and treatments while maintaining regulatory rigor. Provisional registration grants time-limited approval based on preliminary clinical data, with sponsors required to submit a confirmatory clinical study plan. The initial approval period lasts two years, with up to two extensions, allowing a maximum of six years of provisional registration. While these medicines can seek government subsidies, the assessment process remains complex due to the provisional nature of the approval.

During the COVID-19 pandemic, the TGA effectively utilized this pathway to ensure rapid access to vaccines and treatments while upholding safety and quality standards. A total of 26

COVID-19-related products received provisional registration, with five transitioning to full registration. Professor Lawler highlighted the critical balance between accelerated access and robust regulatory oversight, emphasizing the importance of pre-submission meetings and horizon scanning in preparing for emerging technologies. He also discussed Australia's role in supporting regulatory capacity-building in neighboring countries, aiding vaccine distribution and emergency use approvals.

Second Keynote Speaker

Mr. Koga discussed Japan's strategies to enhance access to medicines while maintaining high regulatory standards. He emphasized key challenges, such as balancing early access with rigorous review and addressing the complexities of rare disease drug development. Japan has implemented various regulatory pathways to facilitate access, including priority review for serious conditions and orphan drugs, conditional approvals for treatments with limited trial data, and the Sakigake system for breakthrough therapies. Additionally, Japan has established a consultation center to support orphan and pediatric drug development and is enhancing regional collaboration through the PMDA Asia Training Center and the PMDA overseas offices.

Key enablers for improving access to medicines include accelerated approval pathways for orphan and pediatric drugs, streamlined regulatory processes to enhance communication with applicants from early phase of the development, and efforts to strengthen regulatory capacity through global collaboration and training. These initiatives aim to facilitate universal access to safe, effective, and high-quality medicines while ensuring a robust regulatory framework. Mr. Koga stressed the importance of international cooperation in addressing shared challenges and advancing regulatory science to support timely access to innovative treatments.

Third Keynote Speaker

Dr. Raine highlighted the importance of regulatory reliance as a key mechanism to improve access to medicines by allowing authorities to leverage decisions made by trusted regulators. She emphasized that reliance helps remove regulatory barriers, accelerates approvals, and fosters mutual learning between high- and low-resource regulatory environments. The approach is widely recognized by institutions such as the WHO and ICMRA as an efficient strategy for strengthening regulatory systems. Drawing from the MHRA's experience, she outlined how the agency initially relied on European Commission (EC) decisions before expanding its recognition to multiple international regulatory authorities. In 2023, approximately 87 products were approved under this system, with a third being new active substances, significantly reducing approval timelines to 7-8 weeks.

Dr. Raine identified key success factors for effective reliance, including transparency and data-sharing among regulators, robust post-marketing surveillance, and alignment with health technology assessments and national healthcare readiness. She underscored the importance of building trust among regulatory authorities to ensure the reliability of reliance-based decisions. Looking ahead, she highlighted priority areas where reliance could have the greatest impact, such as rare diseases and antibiotic development. Additionally, she emphasized the need to strengthen regulatory science for emerging therapies, including genomics and biomarkers, and leverage the Prequalification of Medicines Program (PQM) to facilitate global regulatory decision-making.

Fourth Keynote Speaker

Dr. Cerqueira provided an overview of the life cycle of medicines in Brazil and Anvisa's role in ensuring access to affordable drugs while maintaining regulatory standards. She outlined the regulatory pathway, where Anvisa evaluates drug safety, efficacy, and quality before granting market authorization. Following approval, the Drug Market Regulation Chamber (CMED) sets price caps for commercialization. Medicines can then be incorporated into the Unified Public Health System (SUS) or the private sector, undergoing additional cost-effectiveness and budget impact assessments. To accelerate drug approval, particularly for rare diseases and innovative treatments, Brazil has implemented prioritization and fast-track resolutions. The reliance procedure, introduced in 2022, allows Anvisa to leverage evaluations from other regulatory authorities, significantly reducing approval time.

Dr. Cerqueira also discussed challenges and market trends related to drug availability in Brazil. Between 2019 and 2023, Anvisa approved 232 new drugs, with nearly half benefiting from prioritization. Notably, 70% of prioritized drugs were commercialized within one year, compared to 35% under standard procedures, with biologic drugs showing better commercialization rates than synthetic drugs. However, around 30% of prioritized drugs were not marketed within the expected timeframe, often due to pricing constraints or delays in commercialization. These findings highlight the need for continuous improvements in regulatory strategies to ensure timely access to essential medicines while maintaining affordability and sustainability in the healthcare system.

Key considerations for ICMRA

The session focused on key issues surrounding patient access to medicine, regulatory strategies, and balancing fast-track approvals with safety and efficacy. Panelists emphasized the importance of reliance mechanisms, international collaboration, and capacity-building efforts. Harmonizing regulatory policies, pre-market authorization cooperation, and post-market surveillance were also emphasized as critical elements in enhancing global access to medicines.

Strategies such as post-marketing surveillance, mandatory follow-up studies for conditionally approved drugs, and the use of real-world data to assess long-term safety and effectiveness were shared. The role of real-world data in regulatory decision-making was also discussed, emphasizing the need for clear withdrawal criteria if safety concerns arise post-approval. The idea of a "one dossier" system was seen as a promising opportunity to streamline regulatory reviews and accelerate access to medicines.

The discussion also addressed the intersection of regulatory approval, reimbursement processes, and patient access, focusing on challenges and potential solutions across different regulatory systems. Medicine shortages and reimbursement delays were identified as major barriers to timely access, especially for emergency-approved medicines

Key takeaways included strengthening post-approval safety measures, enhancing early collaboration between regulators and reimbursement bodies, addressing affordability, building regulatory capacity through training programs, and fostering transparency to maintain public trust. The session concluded with a call for greater international cooperation and proactive planning to improve global medicine access.

Session 3 - Regulatory solutions to address the challenges of AMR and how regulators can work together towards a global plan

Co-Chairs: Ms. Emer Cooke - EMA and Ms. Pamela Aung-Thin – Health Canada (HC)

Ms. Aung-Thin, the Assistant Deputy Minister of the Health Products and Food Branch for HC, opened the session by thanking the organizers and participants. She emphasized the importance of Antimicrobial Resistance (AMR) as a global health issue and introduced the session's focus on how regulatory bodies can combat AMR.

Ms. Aung-Thin highlighted the recent United Nations General Assembly (UNGA) high-level meeting on AMR and the upcoming 2024 World AMR Awareness Week. She noted that AMR is a One Health issue, requiring a multisectoral approach across human, animal, and environmental health.

This session featured two keynote speeches, one delivered by Dr. Cooper Sampson from the World Health Organization (WHO), provided an overview of the 2024 UNGA Political Declaration on AMR and its significance for regulators. The second keynote speech was presented by Dr. Greg German from Unity Health Toronto and the University of Toronto and focused on the current state of research and development in new antimicrobials, as well as emerging therapies that regulators should consider.

In addition to the keynote speeches, the session included two topic discussions. Dr. John Farley from the US FDA's Center for Drug Evaluation and Research (CDER) presented on *The Quadrilateral Group: Can its work be of use to other regulators?* Meanwhile, Dr. Tumi Semete-Makokotlela from South African Health Product Regulatory Authority (SAHPRA) discussed *Regional Specificities in a Heterogeneous World: Africa's Priorities.*

The session concluded with a panel discussion and Q&A, led by co-chairs with additional insights from the two presenters, Dr. June Raine (MHRA) and Dr. Carlos Lima Alves from the Portugal's Medicines and Health Products Authority (INFARMED).

First keynote Speaker

Dr. Sampson provided a comprehensive overview of the 2024 UNGA Political Declaration on AMR and its critical implications for regulators. He highlighted the alarming global impact of AMR, with 1.14 million deaths annually and an associated economic burden of $855 billion in healthcare costs and productivity losses. Without decisive action, AMR-related deaths could reach 39.1 million between 2025 and 2050. Despite these dire projections, only 10% of countries have allocated funding for their national AMR action plans. Dr. Sampson emphasized the importance of the UNGA Political Declaration, which calls for a unified approach involving both society and government. He stressed the pivotal role of regulators in addressing AMR, particularly in ensuring access to quality antimicrobials, combating substandard medicines, and fostering collaboration between human, veterinary, and agricultural sectors.

Dr. Sampson also discussed the formation of the RAGMAR (Regulators Against AMR Network) initiative following the first global summit of regulators in 2023. This network,

which currently includes human and veterinary regulators, aims to strengthen global coordination. Looking ahead, Dr. Sampson emphasized the need to expand RAGMAR to include agricultural and environmental regulators, enhance benchmarking for regulatory systems, particularly in animal health, and plan the second Global Joint Summit of Regulators. His presentation underscored the urgent need for regulatory collaboration to effectively implement the UNGA Political Declaration on AMR.

Second keynote Speaker

Dr. German provided an insightful overview of phage therapy as a promising alternative to antibiotics for treating bacterial infections, particularly in the context of antibiotic resistance. Bacteriophages, viruses that specifically target and infect bacteria, offer potential solutions for infections that no longer respond to traditional antibiotics. However, the speaker highlighted significant challenges in the field, including difficulties in classifying phages as drugs, standardizing susceptibility testing, and navigating complex regulatory frameworks to secure approval for phage-based treatments.

Despite these hurdles, early clinical evidence shows promising results, particularly in treating urinary tract infections (UTIs), with high rates of clinical cure and bacterial eradication. The speaker also emphasized the importance of global collaboration, referencing initiatives like the Global Clinical Phage Rounds, which facilitates discussions between researchers and regulatory bodies. Efforts in Canada and Australia were also mentioned as key players in advancing phage therapy. Looking ahead, the speaker discussed ongoing clinical trials, the development of susceptibility testing guidelines, and regulatory surveys aimed at improving accessibility and scientific understanding of phage therapy. The talk concluded with an invitation for stakeholders to engage in regulatory discussions to further enhance global coordination and progress in this field

First Presentation

Dr. Farley provided an overview of the Quadrilateral Group's work in facilitating antibacterial and antifungal drug development through interagency collaboration. He highlighted the challenges faced in this field, such as the economic limitations of antimicrobial development and the difficulty in designing trials for life-threatening infections with rare resistant pathogens. Farley explained how regulatory agencies play a crucial role in harmonizing clinical trial designs across different regions to ensure that drug development programs satisfy the requirements of multiple regulatory authorities.

The Quadrilateral Group, initially formed in 2016, now includes discussions with HC, focusing on harmonizing recommendations for the development of treatments for serious infections like complicated urinary tract infections. Farley emphasized the importance of updated guidance and shared trial design standards, which have led to regulatory certainty for the industry. Looking ahead, the group plans to tackle topics such as pediatric drug development, antifungal drug development, and moving nontraditional therapies like phage therapy from compassionate use to formal clinical development.

Second Presentation

Dr. Senoko highlighted that South Africa is taking a comprehensive approach to combating AMR through its One Health strategy, which integrates human, animal, and environmental health efforts. The country's strategy is governed by the Ministerial Advisory Committee on AMR, with provincial and district Antimicrobial Stewardship Committees ensuring implementation across all levels. Key components of the strategy include a strong focus on data-driven surveillance and public awareness campaigns to address AMR. However, South Africa faces significant challenges, notably the dual regulatory system for antimicrobials. The Stock Remedies Act (1947) governs antimicrobials for livestock, while the Medicines and Related Substances Act applies to other uses, creating regulatory inconsistencies and loopholes that hinder effective oversight.

The consequences of this dual regulation are far-reaching. A large percentage of antibiotics in agriculture are sold over the counter, leading to misuse, with farmers self-prescribing without veterinary consultation. Additionally, the illegal trade and use of unregistered antimicrobials, such as colistin, has increased, exacerbated by post-COVID black market activity. This misuse, combined with overprescription and non-compliance with treatment regimens, has heightened the risk of antimicrobial resistance. To address these challenges, South Africa is implementing several strategic actions, including the creation of a Risk Assessment Task Force, engagement with the Agriculture Ministry to unify regulations, and the development of a pharmacovigilance system for tracking and regulating antimicrobial use. These efforts aim to strengthen surveillance, harmonize regulations, and curb the misuse of antimicrobials, positioning South Africa to effectively tackle AMR.

Panel Discussion

Dr. Raine highlighted the country's strong commitment to addressing antimicrobial resistance (AMR) as a top priority. She emphasized the importance of international collaboration, particularly following the progress made at UNGA, and the establishment of the Independent Panel on Evidence for Action against AMR, a significant outcome of the political declaration. The UK has implemented a National Action Plan that adopts a cross-sectoral, One Health approach, integrating efforts across human, animal, food, and environmental health sectors. The plan focuses on preventing infections, optimizing antimicrobial use, and advancing research and innovation.

Looking ahead, the centennial of penicillin in 2028 will mark the launch of the Fleming Initiative, which aims to fund international Fleming Centers to coordinate global efforts in combating AMR. Dr. Raine underscored the critical role of regulators in providing early scientific advice and fostering international partnerships throughout the product lifecycle. The UK is also working on developing diagnostic standards and exploring new frontiers in microbiome research and phage therapy. She likened the collective effort against AMR to conducting an orchestra, stressing that collaboration is essential to maximize the impact of AMR initiatives. The speaker concluded by stressing the urgent need for action in this critical global health challenge.

Dr. Alves, a board member of Portugal’s regulatory agency Infarmed and an infectious disease specialist, discussed the global, multidisciplinary challenge of AMR and the need for a One Health approach. He stressed the importance of collaboration between human health,

veterinary, food, agricultural, and environmental sectors to address AMR effectively. Key points from his talk included the critical role of monitoring and surveillance in tracking antibiotic consumption and detecting emerging microbial threats. He referenced how unusual antibiotic consumption patterns were instrumental in the early identification of AIDS. Dr. Alves also highlighted the need for innovation in diagnostics, such as fast and accurate point-of-care testing, and emphasized the role of vaccines in reducing bacterial infections and preventing unnecessary antibiotic use.

In addition, Dr. Alves underscored the importance of research and development for new antibiotics, especially "reserve" antibiotics, and called for regulatory support in overcoming antibiotic shortages. He also addressed the ongoing challenge of combating falsified and substandard drugs, urging stringent regulatory oversight. While exploring alternatives to antibiotics, Dr. Alves pointed to phage therapy as a promising option but acknowledged the regulatory complexities involved. He suggested using regulatory sandboxes to facilitate phage therapy development. Finally, Dr. Alves highlighted environmental concerns, noting that antibiotics entering the environment through waste or improper disposal contribute to AMR. He concluded by recalling the historical scarcity of penicillin, warning that antibiotic residues in the environment continue to pose a significant risk.

During the Q&A session, the co-chairs highlighted key insights and challenges raised by the speakers. Dr. Sampson addressed two main issues: the gap between AMR policies, their implementation and ensuring equitable access to quality antimicrobials. He stressed that regulatory agencies must take proactive steps to close these gaps and ensure timely access to essential medicines. The session also focused on the importance of regulatory involvement in global initiatives, including the need to update the Global Action Plan on AMR and optimize antimicrobial use.

The co-chairs emphasized the need for stronger regulation, particularly in the context of emerging treatments like phage therapy, which requires tailored regulatory frameworks. They also discussed the possibility of a unified development plan for antimicrobial products and the importance of inter-agency collaboration, particularly following the lessons learned from the COVID-19 pandemic.

Key considerations for ICMRA

The session highlighted critical discussions and insights on combating antimicrobial resistance (AMR) through a coordinated global approach. Key takeaways included the urgent need for regulatory bodies to bridge the gap between AMR policies and their implementation, ensuring equitable access to quality antimicrobials. The session concluded with a call to action for regulators to apply lessons from the COVID-19 response to AMR efforts, ensuring global cooperation and proactive engagement in antimicrobial development and responsible use within a One Health framework.