ICMRA Statement on Innovation

April 2019

What is ICMRA?

The International Coalition of Medicines Regulatory Authorities (ICMRA) is a global alliance of the leaders of medicines regulatory agencies. It acts on a voluntary basis, providing strategic leadership and coordination in regulatory approach and thinking. ICMRA works to address current and emerging human medicine regulatory and safety challenges globally. There are 27 participating countries represented by the heads of medicines regulators from across the regions, with the World Health Organisation participating as an observer.

The changing innovation environment and regulatory challenges

The development of innovative medicines is essential for continued progress in the prevention and treatment of disease. In the last few years, this has been highlighted by significant advances that have potential to save lives or dramatically alter life expectancy such as developments in immuno-oncology or curative treatments for diseases previously associated with fatalities such as hepatitis C.

The research and innovation environment for medicines continues to rapidly develop new products, technologies, and production models that are potentially complex, disruptive to current regulatory systems and hugely transformative for the delivery of therapeutic benefits to patients and the health system. Examples include the use of 3D printing to print human tissues and organs, genome editing to advance drug discovery and development and treat diseases, and artificial intelligence to assist in detecting and diagnosing disease and in monitoring treatment. While the existing novel licensing pathways have seen positive results in providing timely patient access, current and upcoming innovations will continue to challenge our regulatory frameworks.

More adaptive and flexible regulatory approaches are vital to keeping pace with innovation and enabling the delivery of novel and safe treatments for our patients. This is particularly pertinent and key to the delivery of treatments in areas of high-unmet need.

Medicines regulators at national, regional and global levels can, at an early stage, identify future innovation, key scientific uncertainties, and the regulatory barriers that will need to be addressed to enable market access. However, advising and engaging with our legislators and policy makers, in addition to addressing internal organizational capabilities and culture, to determine solutions, is key to ensuring success and delivery for patients and healthcare systems.

ICMRA's Role in Supporting Innovation

In recognition of the opportunities presented by the fast-paced and continuously evolving pharmaceutical sector, ICMRA includes innovation as one of its key strategic priorities. The establishment among its membership of a global approach for coordination on innovation has been a key outcome. This includes: utilisation of best practices for early horizon scanning; evaluation of the applicability of existing regulatory approaches including novel licensing systems; identification of potential barriers and future expertise needs. Our work in this area continues to highlight the critical need from the perspective of regulators across the globe for flexible regulatory frameworks with better adaptive capability.

It is incumbent on all regulators, both amongst ICMRA members and in the broader network, to continue to build capacity in order to embrace the development of new standards and processes that will enable these innovations to safely proceed to be developed and continuously improved as the technology evolves and we advance our knowledge and understanding of products and processes.

Harnessing Innovation to better support patients and healthcare systems

In order to realise the benefits of innovations for disease prevention and treatment, potential for better resource utilisation in healthcare systems, and possibilities to reduce costs of healthcare provision, there is a need for dialogue between regulators and legislators and policy makers on future approaches to regulation. Translating dialogue into action and implementing changes in approach at an early stage, represents a unique opportunity for us as health stakeholders who have a collective responsibility for delivery of better patient outcomes.

ICMRA's Call to Legislators and Policy Makers

It is imperative that our regulatory system continues to focus and find new ways to increase flexibility and adaptability to fulfil its role in facilitating safe and timely access to innovation for improved healthcare outcomes. ICMRA calls for regulators, legislators, and policy-makers to work together to promote and put to action

- *Developing greater awareness of trends and challenges in innovation to identify the necessary approaches and evidence standards that will facilitate innovation and timely access to medical products while protecting patient safety.*
- *Enabling a regulatory system that is forward looking and continually evolving to anticipate challenges and provide timely solutions to support innovative research and product development.*
- *Ensuring that regulation/policy and product lifecycle oversight is flexible and adaptable, with the capacity to remain fit for purpose when applied to current and future innovations.*
- *Strengthening international collaboration in the areas of advanced technologies and other innovations to maximise the early potential for harmonised coherent global approaches that can support regional and local regulation.*