



## **ICMRA statement on COVID-19**

*28 April 2020*

The International Coalition of Medicines Regulatory Authorities<sup>1</sup> (ICMRA) has pledged its collective support in countering the global COVID-19 pandemic:

It is together, in the face of this unprecedented crisis of global proportion, that we can find solutions. We, ICMRA members have an important role to play in supporting the worldwide effort. We have stepped up our global collaboration to facilitate and expedite the development and evaluation of diagnostics and therapeutics, including possible vaccines, against SARS-CoV2.

### **ICMRA actions**

In the last weeks, ICMRA held 3 virtual meetings with more than 100 participants each from our 29 members, with our scientific experts, and observers to progress together:

- 1) the regulatory considerations for anticipated COVID-19 vaccine candidates to advance regulatory understanding and convergence, and facilitate first-in-human studies (data requirements for Phase 1 COVID-19 vaccine trials, <http://www.icmra.info/drupal/news/March2020>);
- 2) the development of potential therapeutics, clinical trials and compassionate use programmes for COVID-19 (<http://www.icmra.info/drupal/news/9April2020>); and
- 3) use of real-world evidence and observational studies (i.e., how data generated during clinical practice could complement the evidence from clinical trials with potential therapeutics or vaccines against COVID-19, <http://www.icmra.info/drupal/news/16April2020>).

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<sup>1</sup> ICMRA is an international executive-level coalition of key regulators from every region in the world. ICMRA brings together the heads of 29 medicines regulatory agencies from every region in the world, with the World Health Organization as an observer, to facilitate access to safe, effective, high-quality products that are essential to human health and well-being. It provides a global strategic focus for medicines regulators and gives strategic leadership on shared regulatory issues and challenges. Priorities include coordinated response to crisis situations.

## **In the battle against COVID-19, we, ICMRA members, are committed to:**

- facilitating and expediting the development of health products by supporting clinical trials for medical devices, treatments, and vaccines;
- working together to ensure the regulatory processes related to COVID-19 are as efficient as possible to support the development and delivery of effective and safe medical products to populations in need worldwide;
- aligning on regulatory requirements and collaborating on accelerated procedures from the development to the approval, including rolling reviews and approval of trials, drugs, biologics and vaccines;
- once a vaccine or therapeutic product is authorized, monitoring the market to ensure that their benefits continue to outweigh any potential risks;
- as the impact of COVID-19 respects no borders, we are committed to equitable access to trials and medicines for the populations affected by COVID-19. When a solution is found, we will take an action together in a global approach;
- working closely to support the rapid development of diagnostic tests for COVID-19, to ensure comparability of results and approaches to implementation.

## **ICMRA recommendations**

- ICMRA Heads of Authorities call on governments, research bodies and academic researchers, ethics committees, and industry, to be cognisant of the need for large, well-designed, controlled clinical trials that are capable of giving robust evidence of the safety and efficacy of proposed therapies for COVID-19. Robust evidence is necessary for regulatory review, one step towards access for affected populations. ICMRA fully recognises the huge pan-global effort at finding appropriate therapies and vaccines. However, poorly designed, underpowered trials, or those without a robust rationale may involve therapies in limited supply and consume limited resources in hospitals and clinical settings. Furthermore, it is essential and ethical that trials most likely to yield interpretable results are prioritised.
- ICMRA Heads of Authorities recognise that COVID-19 is also impacting Low- and Middle-Income Countries' populations which are already at higher risk due to limited capacity and/or capability to manage COVID-19 serious complications. Their access to medicines (vaccines and therapeutics) and medical devices will need to be ensured for ethical reasons of distributive justice. Some of these countries are also at risk of greater disease burden, and a failure to address COVID-19 may result also in large remaining reservoirs of disease, and subsequent serious economic and social disruption and consequences, which will affect all of us in the world.
- ICMRA Heads of Authorities are also committed to working with the pharmaceutical industry companies, distributors and manufacturers to address jointly and collaboratively drug supply issues, shortages and decreased manufacturing capacities. Now is the time for industry to work even more cooperatively, complementing each other in capacity and product diversity, and collaborating to reduce the global and individual consequences of this devastating pandemic.

ICMRA members stand ready and will continue to work together to ensure the regulatory processes related to COVID-19 are adequately efficient to help expedite the development and delivery of medical products of importance in the fight against COVID-19 to populations in need worldwide. We also won't spare our efforts to mitigate drug shortages resulting from the global disruption caused by the pandemic.

ICMRA will communicate progress through regular public statements over the coming weeks and months.