WHO-ICMRA joint statement on the need for improved global regulatory alignment on COVID-19 medicines and vaccines

In view of the large number of COVID-19 vaccines and treatments under development, and their potentially imminent roll-out, the World Health Organization (WHO) and the International Coalition of Medicines Regulatory Authorities (ICMRA) have joined forces to uphold and promote the most rigorous, evidence-based regulatory practices by supporting the alignment of regulatory processes across all countries. As in other areas of the pandemic response, multilateral cooperation between regulatory authorities will be critical in ensuring there is a level playing field, that COVID-19 vaccines and medicines are safe, effective and quality-assured, and that all countries may benefit from such products equitably and at the same time. This joint statement commits each organization to a series of actions to make this happen.

ICMRA and WHO continue to join forces in collaborating to address the unprecedented global health challenges related to COVID-19 pandemic, affecting so many people in the world.

These challenges are best addressed by working together to ensure existing rigorous scientific standards of review and oversight are maintained, while still giving patients access to safe and effective medical products at the earliest time possible

Regulatory authorities for medical products, including medicines and vaccines, have the responsibility to approve quality assured, safe and effective products based on robust and reliable data.

The regulatory approval should be based on an independent scientific assessment of the balance of benefits and risks.

Robust and reliable data on efficacy and safety to support market approval of medicines and vaccines are best collected through randomized controlled clinical trials which control for bias, meet Good Clinical Practice standards, respect the rights, autonomy and safety of clinical trial participants, and can be audited.

To ensure patients have fast access to safe and effective medicines and vaccines, WHO and ICMRA, together with other stakeholders including public health institutions, are committed to the following actions:

- Working to prioritise well-designed clinical trials that will provide robust and reliable results.
- Ensuring that there are meaningful and scientifically sound endpoints and safety data of sufficient duration in clinical trials;
- Sharing data between regulators in real time to facilitate multi-country approvals;
- Putting in place processes and policies utilizing the principles of regulatory agility by ICMRA members and WHO member states, providing an agile and rapid response to the global emergency;
- Committing to full transparency of clinical trial results to support regulatory decisions, as well as ensuring public trust in authorities and confidence in vaccines
- Working together to prevent and/or mitigate shortages of critical medicines and vaccines;
- Continue working together once these COVID-19 therapies and vaccines are

authorized and used to monitor their use, and identify, communicate and mitigate any safety or efficacy issues which may arise;

- Reduce the risks associated with unproven treatments, potentially fraudulent and false claims, which endanger patients' lives.