Biopharmaceutical Industry Statement on ICMRA workshop on enabling manufacturing capacity in the COVID-19 pandemic

On 7 July 2021, the biopharmaceutical industry welcomed the opportunity to join the International Coalition of Medicines Regulatory Authorities (ICMRA) in a workshop focused on expanding manufacturing capacity for COVID-19 medicines and vaccines. This workshop provided a platform to collectively explore the range of activities associated with post-approval site transfers and review the regulatory flexibilities implemented by ICMRA members during the pandemic. Solutions discussed reflected the spirit of collaboration, co-operation and co-creation which has featured so strongly between all partners seeking to respond to the pandemic and the global public health needs.

As noted by ICMRA in the Virtual Workshop Report on Enabling Manufacturing Capacity in the COVID-19 Pandemic, several common 'enablers' to facilitate the use of regulatory flexibilities resulted from the National Regulatory Authority (NRA) and industry dialogue. These enablers consist, for example, of open communication on dossier submissions between national regulatory authorities and biopharmaceutical companies; illustration of product/process knowledge including relevant manufacturing experience; and good manufacturing compliance. While these enablers provide the foundation for improved implementation of regulatory flexibilities, building upon these is critical to enhance the current pandemic response and rapidly increase supply of COVID-19 therapeutics and vaccines.

To this end, the biopharmaceutical industry believes that there are several, specific priority recommendations, that if implemented more broadly by ICMRA Members, would help to reach the objectives of the workshop: 1) streamline stability testing requirements; 2) embrace alternate process validation approaches; 3) increase utilization of and harmonize approaches to inspection alternatives; and 4) enhance collaborative review and reliance practices for initial registration and post approval submissions.

The workshop dialogue highlighted the challenges experienced by biopharmaceutical companies surrounding data generation, dossier preparation and submission, and pre-approval site inspections that result from inconsistent regulatory requirements and processes globally. Additional barriers were also identified that impede the rapid increase of manufacturing capacity, such as raw materials, supply constraints and workforce readiness.

The biopharmaceutical industry is of the opinion that striving towards greater use of reliance and science- and risk-based approaches for exploring, adapting and implementing regulatory flexibilities between NRAs would help to minimize the impact of these barriers on the manufacture of COVID-19 medicines and vaccines.

The biopharmaceutical industry looks forward to collaborating with ICMRA on the upcoming pilots outlined in the workshop report to support collaborative assessments for post approval changes and foster innovative approaches for inspections while encouraging greater use of regulatory reliance.

In their corresponding Statement on Pre-Requisites for Regulatory Flexibility in Pharmaceutical Manufacturing Change Management, ICMRA called on the biopharmaceutical industry to 'continually demonstrate their commitment to quality, striving for better product and process knowledge, ensuring GMP compliance, and implementing an effective PQS (Pharmaceutical Quality System)'. The biopharmaceutical industry remains committed to patient safety and product quality by implementing and adhering to science-based standards for product development and manufacturing, as well as developing and maintaining robust quality systems that track and describe all aspects of a facility's manufacturing operations.

The biopharmaceutical industry stands ready to work with ICMRA, individual NRAs, and other stakeholders to advance and implement science- and risk-based regulatory agilities to enable the rapid increase of manufacturing capacity for COVID-19 therapeutics and vaccines as well as facilitate timely access to these critical products for patients around the globe.

ICMRA workshop resources:

- Statement from industry associations (7 July)
- Workshop recording
- Workshop report

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