



COVID-19 Biopharmaceutical Industry - Regulatory Guiding Principles

On 14 May 2020, we released our first Regulatory Guiding Principles in the unprecedented and unknown context of the COVID-19 pandemic. One year on and we are still facing the impact of this public health emergency, yet we have seen many advancements and successes. New vaccines against COVID-19 are now available, and multiple new therapeutic medicines are in various stages of the pharmaceutical pipeline. The timelines and pressure behind research and development efforts at such a global scale have never been seen before.

With all the progress that has been made against COVID-19, we risk losing sight of the other activities that transpired to ensure continued biopharmaceutical research, patient supply and access to medicines and vaccines for other conditions than COVID-19. Biopharmaceutical companies were operating and manufacturing in an environment with supply chains that were greatly impacted.

One year ago, we reiterated our continued commitments to four principles focusing on partnership and collaboration, progressing research, maintaining supply, and meeting quality and safety standards. Today, we are still honoring those commitments and are working to implement the best practices and lessons learnt by building stronger systems for the future of global health. The importance of these Regulatory Guiding Principles is clearly evident in what has been achieved during the past, very challenging year.



Working in partnership and collaboration with national regulatory authorities (NRAs) to define the best science-based regulatory strategies for ensuring the availability of COVID-19 medicines and vaccines

- We are engaging with NRAs and regulatory coalitions to provide input, as well as feedback, on regulatory agilities, streamlined processes, rolling reviews and reliance principles implemented to accelerate the development and registration of COVID-19 medicines and vaccines. These lessons learned, along with further development and use of digital technologies, will help to modernize the current regulatory environment to better adapt to scientific and technical innovations in a sustainable fashion while providing best practices for future pandemic preparedness.



Progressing research into new treatments and prevention of other conditions

- Lockdowns, movement restrictions, and stay-at home recommendations redirected health resources to the front line and away from new and ongoing clinical research for non-COVID-19 treatments. Patient enrollment in new clinical trials and access to existing clinical research sites were initially affected. Keeping participants safe and maintaining clinical trial integrity were priorities and implementation of new technologies like remote monitoring helped improve our recruitment of volunteers, clinical trials conduct, and monitoring and data capture.



Maintaining supply of medicines and vaccines

- The manufacture of a medicine frequently requires more than 200 material components, along with a range of technologies. While an initial surge in global demand led to some acute shortages for these components, supply chains overall demonstrated significant resilience during the pandemic. We will continue to work with our partners to identify solutions that address the resilience and reliability of global supply as supported by predictable and agile regulatory processes and requirements.



Ensuring all our medicines and vaccines continue to meet appropriate standards for quality and safety

- Quality manufacturing and patient safety monitoring are fundamental to our work and to public health. Even though the biopharmaceutical industry experienced various disruptions to 'business as usual' during the pandemic, quality, safety and efficacy of the medicines and vaccines we manufacture remained a key priority. Engagement with regulatory stakeholders will continue to ensure that quality and high-level standards are met.

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IFPMA represents research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry's 2 million employees discover, develop, and deliver medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.

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