COVID-19
Biopharmaceutical Industry – Regulatory Guiding Principles

During these unprecedented times, it is essential that we all come together to contribute to the development of medicines and vaccines for treatment and prevention of COVID-19

Many activities, undertaken by governments, national regulatory authorities (NRAs), academia, global health stakeholders and the biopharmaceutical industry, are helping to identify, research, develop and manufacture at scale these vital technologies under immense time pressure.

While resources are being committed to address the pandemic, other equally important efforts must continue for the benefit of patients globally beyond COVID-19. Access to existing medicines and vaccines for treatment and prevention of other conditions, like diabetes, cancer and measles, must continue. Clinical research into new options and treatments for serious and life-threatening diseases and unmet medical needs should be preserved.

Despite the huge impact caused by COVID-19, the R&D-based biopharmaceutical industry must maintain and indeed increase the supply of medicines and vaccines to the best of our ability to patients at a time when 'normal' production, supply chains and business operations are adversely impacted and massively challenged.

With a need for increased speed and a 'new' normal comes unprecedented pressure on biopharmaceutical manufacturing, which we are committed to meeting whilst not affecting patient safety and quality.

Therefore, we would like to reiterate our continued commitments to:

WORKING IN PARTNERSHIP AND COLLABORATION WITH NRAs TO DEFINE THE BEST SCIENCE-BASED REGULATORY STRATEGIES FOR ENSURING THE AVAILABILITY OF COVID-19 MEDICINES AND VACCINES

Implementing new principles (e.g. regulatory reliance and mutual recognition) and enhancing existing approaches for clinical research, pharmaceutical production and advancement of new COVID-19 medicines and vaccines are critical for global public health.

PROGRESSING RESEARCH INTO NEW TREATMENTS AND PREVENTION OF OTHER CONDITIONS

We are committed to adhering to the best principles for conducting clinical research and ensuring the continuation of ongoing clinical trials for promising, non-COVID-19 treatments.

MAINTAINING SUPPLY OF MEDICINES AND VACCINES

Enabling continuity of manufacturing and availability of product supply is imperative for public health. Globally integrated supply chains, which ensure quality, safety and innovative approaches for distribution across the health sector, may be critically impacted by operational disruptions. We work to find solutions that address potential bottlenecks and barriers thereby avoiding disruptions that could jeopardize access to treatments..

ENSURING ALL OUR MEDICINES AND VACCINES CONTINUE TO MEET APPROPRIATE STANDARDS FOR QUALITY AND SAFETY

Patient safety and product quality are key priorities for the biopharmaceutical industry and are intrinsic to what we do. We routinely engage with regulatory and standard-setting bodies in the development and implementation of guidelines for the quality and safety of medicines and vaccines. We also monitor the use of our medicines and vaccines with patients to safeguard and promote public health.