Statement

Global regulators and coalition of pharma and vaccine manufacturing associations come together to discuss COVID-19 pandemic response

On 7 July 2021, the International Coalition of Medicines Regulatory Authorities (ICMRA) is hosting a (virtual) workshop titled **'Enabling Manufacturing Capacity in the COVID-19 Pandemic'** [link] with representatives from the leading association bodies representing biotech firms, developing and industrialized countries vaccine manufacturers, as well as innovative biopharmaceutical, generic and biosimilar companies.

This first workshop with ICMRA members is an opportunity for the biopharmaceutical and vaccines industry to discuss and harmonize the regulatory strategies, approaches and tools that can enable pharmaceutical product manufacturers to increase manufacturing capacity even more rapidly for the production of COVID-19 vaccines and therapeutics to meet global demand. It will also focus on the considerable ongoing efforts already underway since the beginning of the coronavirus pandemic to avoid or mitigate shortages of vaccines and therapeutics for non-COVID-19-related products.

The workshop is a welcome opportunity and an important platform to share emerging best practices and offer solutions in 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. The biopharmaceutical and vaccine industry appreciates the steps that ICMRA and individual national regulatory authorities have taken during the current public health emergency to exercise appropriate science and risk-based regulatory agilities and flexibilities to support the expedited development and review of COVID-19 vaccines and therapeutics leading to emergency use or temporary authorisations while protecting patient safety and product quality.

The industry associations that have come together to contribute to the workshop fully support these initiatives and believe there are opportunities to build on these ongoing efforts to further enhance current approaches to the regulatory oversight of post-approval manufacturing changes and manufacturing facilities to facilitate the rapid increase in manufacturing capacity for COVID-19 therapeutics and vaccines.

The biopharmaceutical and vaccines industry will present case studies providing an overview of the regulatory challenges experienced that hindered their ability to scale up quickly, along with experience of and recommendations for science- and risk-based approaches that facilitated timely patient access to quality medicines and vaccines.

This workshop is organized with the following industry associations:

- Association of the British Pharmaceutical Industry ABPI
- Biotechnology Innovation Organization BIO
- Developing Countries Vaccine Manufacturers' Network DCVMN
- European Federation of Pharmaceutical Industries and Associations EFPIA
- International Federation of Pharmaceutical Manufacturers and Associations IFPMA
- International Generic and Biosimilar Medicines Association IGBA
- Japan Pharmaceutical Manufacturers Association JPMA
- Medicines Australia
- Pharmaceutical Research and Manufacturers of America PhRMA
- Vaccines Europe.

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