



IFPMA, PhRMA, EFPIA, Vaccines Europe, BIO, ICBA Statement

Innovative biopharmaceutical industry comment on COVID-19 vaccines dosing strategies and recommend following the science

Geneva, 13 January 2021, With the first COVID-19 vaccines authorized by regulatory authorities and administered to the public, the biopharmaceutical industry, including leading vaccine makers, recognize that a critical new phase of the COVID-19 pandemic has begun. Collaboration among the global community has resulted in safe and efficacious vaccines being authorized by stringent regulatory agencies, which are already being manufactured and distributed. Additional vaccines are expected to follow.

The biopharmaceutical industry acknowledges the considerable challenges governments are facing to urgently address the enormous strain the pandemic is placing on healthcare systems, societies and economies. In light of the urgent need to reach as many people as possible with COVID-19 vaccines, there are emerging discussions regarding dosing strategies that may not be supported by the authorized labeling or published clinical data.

The biopharmaceutical industry commits to work in partnership with regulatory agencies and recommending bodies to gather further clinical data on several ongoing scientific questions with regard to COVID-19 vaccines. The innovative biopharmaceutical industry believes that vaccine deployment strategies should be based on the outcome of these continuing clinical studies and the evolving knowledge. Therefore, the biopharmaceutical industry supports adhering to the dosing that has been assessed in clinical trials and urges that any changes from the tested and approved vaccine dosing and vaccination schedules for COVID-19 vaccines should follow the science and be based on a transparent deliberation of the available data.

It is vital to preserve, build and sustain public confidence in COVID-19 vaccination by continuing to make and communicate policy decisions based on robust scientific evidence. Only then can we bring this pandemic to an end.

The biopharmaceutical industry will continue to develop and test vaccine candidates for COVID-19 through a sound, scientific and deliberative process. Vaccine manufacturers have pledged to only submit vaccine candidates for approval or emergency use authorization after demonstrating safety and efficacy in clinical trials that are designed and conducted to meet the requirements of regulatory authorities¹. Our collective membership remains committed to continuing to share our findings with regulatory authorities, public health experts and academics to assist with evidence-based decision-making.

¹ IFPMA August 2020 statement on [Innovative vaccine industry strongly committed to rigorous regulatory standards for approval of COVID-19 vaccines](#)