

Statement from Organization of Pharmaceutical Producers of India

May 10, Mumbai/New Delhi:

OPPI member companies are fully committed to developing newer and improved treatment options to help respond to COVID-19 pandemic, ensuring that innovative therapies are available equitably and expeditiously. Our member companies have been continuously reviewing their drug and vaccine portfolios, with their scientists keep searching for potentially useful assets that could help develop new and repurposed treatments and vaccines to fight the novel coronavirus. As a result, many vaccines as well treatment options are now available that further demonstrates our commitment.

Innovation is the bedrock on which the research-based pharmaceutical industry is founded. Reliance on innovation is what fosters the global pharmaceutical industry and has helped develop not one but several COVID-19 vaccines within months of the onset of the pandemic.

We are cognizant that with the rising COVID-19 cases in India and in other developing nations there is an urgency to rapidly produce greater quantities of COVID-19 vaccine. Vaccine manufacturing is a complex process and scaling up capacities involves the transfer of critical knowhow.

We believe this can only be optimally achieved when vaccine manufacturers are able to scale up capacities at their production sites and/or through licensing agreements with other manufacturers, along with supply agreements with governments to make required quantities deployed rapidly and reliably.

Waiving of intellectual property rights will neither lead to increased production of vaccines or increased deployment nor practical solutions to fight the virus of COVID-19 vaccines since IP is not the barrier to adequate availability of vaccines in India. Waiving of intellectual property rights could impact patient safety by opening doors for counterfeit vaccines to enter the supply chain. There is also a risk of diverting precious raw materials and ingredients necessary to produce the vaccines from high quality manufacturers to inexperienced ones, further disrupting the existing manufacturing capacity. It may also stifle further investment in R&D that are instrumental in delivering new vaccines and treatments against new virus variants.

With indigenously developed and manufactured vaccines already available for distribution, and additional global vaccines on the way, it is pertinent to determine and resolve actual barriers to increased availability in order to ensure that a larger number of Indian citizens are immunized against COVID-19 at the earliest.

Shouldering our responsibility in this hour of crisis, OPPI member companies have engaged in technology transfers in a series of vaccines and therapies:

- **AstraZeneca** has transferred technology to Serum Institute of India, the world's largest vaccine manufacturer, for the manufacture in India of its vaccine *AZD1222*, named "*Covishield*."
- **Pfizer** was one of the first to approach Indian regulators seeking Emergency Use Authorisation for its Pfizer-BioNTech mRNA vaccine *BNT162b2*.
- **Johnson & Johnson** has entered into a partnership with Indian vaccine maker Biological E. Limited for manufacturing its vaccine candidate, *Ad26.COV2.S*.
- **MSD** has entered into voluntary licensing agreements for its antiviral drug *molnupiravir* with six established Indian generics manufacturers.

- **Gilead** has signed non-exclusive voluntary licensing agreements with 7 generic pharmaceutical manufacturers in India to ensure higher supply of its antiviral drug *remdesivir*.
- **Roche** has increased its manufacturing capacity and supply by ramping up production network for *Actemra* (brandname *Tocilizumab*) and has been collaborating with its Indian business partners to increase its availability.
- **Eli Lilly** has granted voluntary licenses to multiple Indian companies including Cipla Ltd., Lupin Ltd. and Sun Pharmaceutical Industries Ltd. to manufacture its anti-viral drug *Baricitinib*, both as a formulation and API.

The pharmaceutical industry will not waiver in its commitment to provide safe, effective and quality vaccines and therapeutics. We will continue to leave no stone unturned to further scale up manufacturing of COVID-19 vaccines and medicines through collaboration and partnerships as, we believe, no one is safe until everyone is safe.

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About OPPI

The Organisation of Pharmaceutical Producers of India (OPPI) established in 1965, represents the research-based pharmaceutical companies in India. OPPI remains committed to supporting the nation's healthcare objectives and collaborating with all stakeholders to find sustainable solutions. OPPI believes the need for innovation must be balanced with the necessity for more accessible medicines, within a robust IP environment. For more information, please visit <https://www.indiaoppi.com/>

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