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Editorial

REGULATORY PATHWAYS FOR COVID-19 VACCINE APPROVAL: GLOBAL PERSPECTIVE

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The pandemic SARS-CoV-2 is a powerful reminder of the ability of infectious diseases to sicken, kill and disrupt the human kind, even at the time of most technologically advanced era. The work on vaccine solution begins within weeks of China's initial COVID-19 outbreak and notification of World Health Organization (WHO) on December 31, 2019. This was possible due to rapid announcement of the outbreak, early publication of viral sequence and quick announcement of funding of grants (in January 2020) for vaccine development by the Coalition for Epidemic Preparedness Innovations (CEPI), the global organization for control of epidemic diseases. The tireless efforts made by various research organizations around the globe, resulted over 200 vaccine candidates, in various stages of development (in just 6 – 18 months timelines) with over 50 vaccines in human clinical trial, and around 18 in efficacy testing.

Before any vaccine can be approved for human use, it has to undergo rigorous testing by its developer and then scientific evaluation by various regulatory authorities. When a candidate vaccine make it to human clinical trials, after satisfactory pre-clinical study results, they first need to pass through Phase-I trials primarily to test vaccine's safety, determine doses and identify any potential side-effects in a small number of peoples (20 – 100). Phase-II trials further explore safety and start to investigate efficacy in larger groups of participants. In Phase-III trials, a much larger, usually thousand or tens of thousands of volunteers/ participants are used to confirm and assess the effectiveness of the vaccine and test whether there are any rare side-effects that only show up in large groups of people. The final stage i.e. Phase-IV trials is conducted after obtaining national regulatory approval and involves further monitoring of safety-efficacy in a wide population and longer timeframe as a form of post market surveillance.

Vaccines are approved in the country of manufacturing by a National Regulatory Authorities (NRA) like European Medicine Agency (EMA) in European Unions, Food and Drug Administration (FDA) in USA, and Central Drugs Standards Control Organizations (CDSCO) in India. The regulatory authorities in the USA,

Europe, UK and Japan are very stringent, but those in Brazil, South Korea, Indonesia and India are deemed functional, not stringent. Once a vaccine is approved by any NRAs, it can be submitted for WHO pre-qualification (PQ) approval. Upon receipt of application WHO does a second review of all clinical, laboratory and manufacturing data. All vaccines must be prepared following strict GMP (including cGMP) and GLP protocols. WHO also sometimes conduct inspections, and if satisfied, will issue a PQ approval. PQ approval allows various global organizations such as UNICEF or the Pan American Health Organizations (PAHO) to purchase the vaccines for global health use by the organizations like Gavi, the Vaccine Alliance. COVAX is the vaccine pillar of the Access to the COVID-19 Tools (ACT), established by the WHO, the European Commission and the French Govt. WHO PQ is required for COVID-19 vaccines intended for COVAX, which is jointly led by WHO, Gavi and CEPI. Once PQ is granted, hundreds of millions of doses of vaccines from various vaccine manufacturing countries like India, Brazil, South Korea etc. can be bought by UNICEF, which is the largest purchaser of vaccine for Gavi, the Vaccine Alliance. Considering the emergency situation of covid-19 pandemic and issuance of emergency use approvals and marketing authorization by various NRAs, it is not clear whether all countries will seek direct licensing and purchasing from the manufacturers without WHO review and purchase those vaccines directly from manufacturers through bilateral deals.

Vaccines for COVID-19 are developed through fast-tracked procedure globally. Development is compressed in times, applying the existing extensive knowledge on vaccine production. Early scientific advice from regulators also helps speed up vaccine development. Vaccine manufacturers have also expanded manufacturing capacities and large scale production to facilitate vaccine deployment without delay, once approved. In India, the CDSCO has already granted, on 3rd January 2021, restricted emergency use approval for COVISHEILD manufactured by M/s Serum Institute of India (through technology transfer from AstraZeneca/ Oxford University and indigenously prepared COVAXIN, manufactured by M/s Bharat Biotech in collaboration with ICMR and NIV (Pune). Another indigenous vaccine designed and developed by M/s Cadila Healthcare Ltd. received permission for Phase-III clinical trials from CDSCO, Govt. of India. Around the glove, other vaccines that received emergency use approval from various NRAs are- Pfizer/BioNTech's RNA vaccine (UK, USA, Canada, Brazil, Israel, Australia, Japan, Germany, and Singapore), AstraZeneca/Oxford's Viral Vector Vaccine (UK, India, Argentina, Bangladesh, Brazil, Malayasia, Mexico, Nepal, Pakistan, Phillipines, Sri Lanka, Taiwan and Vietnam), Moderna's RNA vaccine (Switzerlandt, UK, USA), Janssen/Johnson & Johnson's Viral Vector vaccine (Australia, Switzerland, UK,

USA), Sinovac's Inactivated vaccine (China), Sinopharm's Inactivated vaccine (China, Saudi Arabia, Bahrain, UAE etc), Gamaleya's vaccine (Sputnik-V) (Russia, India and more than 50 other countries) etc.

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