

Policy Brief

COVID-19 Vaccine in Pakistan

The Ministry of National Health Services, Regulations and Coordination convened a national consultative meeting under the Health and Population Think Tank (HPTT) to deliberate on 'COVID-19 vaccine in Pakistan'. The purpose was to inform policy and put up specific recommendations for the Federal as well as Provincial Governments.

COVID-19- a threat to global public health- initially, emerged in Wuhan, China in late December 2019. Its devastating impact pushed many countries to their limits. Pakistan was not spared either, since the first two cases were reported in Pakistan on 26th February 2020. With its fast spread around the world, WHO had to declare it as global pandemic in March 2020. In order to cope with this global public health emergency, the government of Pakistan promptly responded by establishing a National Command and Control Center. NCOC provided a platform to ministries, provincial governments, and operational entities including Pak Army for inter-departmental collaboration for addressing COVID-19 challenges. In addition, MoNHSR&C has actively played a leading role in making evidence based decisions for the efficient resource deployment and formulating "Government of Pakistan Anti COVID-19 Strategy". Similarly, Health Services Academy contributed in the development of COVID 19 national guidelines/ Standard Operating Procedures; COVID-19 epidemiological modeling, training of healthcare workers, and intensive care units (ICU) doctors. It is evident that a sustainable solution to control the COVID-19 pandemic is an effective COVID-19 vaccine. Therefore, NCOC has commissioned "National Expert Committee for COVID19 Vaccine" to work on a National Vaccine Strategy.

The intense global research and development (R&D) competition to develop the COVID-19 vaccines has been started, since the publication of the genetic sequence of COVID-19 causing virus i.e. SARS-CoV-2, on 11th January 2020. Recently, more than 250 candidates are involved along with several companies in vaccine development. Among them, 26 candidates are in different phases of clinical trials with almost 9 companies leading the race. It is necessary to access accurate data related to vaccine safety, efficacy and side effects for regulatory approval of vaccine dissemination. Amid this competition, It is a critical challenge as this data will be available after phase III clinical trials.

The mandate to allow vaccine or its clinical trials in Pakistan belongs to the Drug Regulatory Authority of Pakistan (DRAP). Under this mandate, the pro-active role of DRAP in guiding regulatory processes for approval of COVID-19 vaccines is important. In Pakistan, National Institute of Health (NIH) uses obsolete technology for the production of few vaccines which needs to be upgraded in term of indigenous vaccine production capacity and technology as pandemics are expected in near future. Along with vaccine production, the indigenous capability to conduct clinical trials locally is also important. COVID-19 has created potential opportunities for Pakistan to conduct clinical trials (in collaboration with other countries) and to capitalize international collaborations for technology transfer, academic exchange and human resource training. After vaccine approvals, its distribution to vulnerable target groups and larger population is another challenge. The current expanded program on immunization (EPI) leads vaccination campaigns for polio, measles, typhoid and others. Their infrastructure is pivotal for COVID-19 vaccination.

As a follow up to the National Expert Committee's recommendations, a wider input from multi-stakeholders was needed to highlight challenges and provide policy input and suggest

priority actions for different stakeholders. HPTT invited national and international technical experts and other relevant stakeholders through its platform to deliberate on following strategic issue:

1. How should the communication strategies be shaped and developed, knowing the perception challenges of COVID-19 vaccine?
2. What is needed to develop fast-track transparent system for approval and registration of COVID-19 vaccine?

The discussion resulted with following action points as a priority.

Priority actions

- **MoNHSR&C** should negotiate prerequisites of cost, volume and regulatory mechanism with leading vaccine producers and those interested in running clinical trials to timely secure vaccines with proven safety & efficacy for its priority groups.
- **MoNHSR&C** to procure WHO prequalified vaccines and their production units should comply with WHO and ICHQ5E standards.
- **MoNHSR&C** to explore possibility of becoming a member of International Coalition of Medicines Regulatory Authorities (ICMRA) to utilize their resources for vaccine related development and implementation.
- **MoNHSR&C** to ensure implementation of strict preventive measures along with vaccination that is so far the only solution considering limited data on vaccine effectiveness.
- **Drug Regulatory Authority of Pakistan (DRAP)** to evaluate safety, efficacy data and follow robust regulatory framework for approval in consultation with international experts group to analyze long-term side effects and clinical impact of vaccines including live attenuated vaccines, which are still unknown.
- **DRAP** to develop fast track registration system, standard operating procedures (SOPs) to prioritize entry of globally approved vaccines in Pakistan with stringent evaluation of both, its clinical & manufacturing site approvals.
- **HEC** to facilitate in identification of target segments for immunization and to channelize subject experts group on its platform for continuous R & D on COVID-19 issues.
- **MoNHSR&C** to develop impactful and target group tailored media communication campaigns for effective communication of COVID-19 vaccine to be disseminated by the media, influencers and relevant stakeholders.
- **NIH** to coordinate COVID-19 clinical trials in Pakistan and enhance its indigenous capacity for filling, labeling and packing of vaccines.
- **NIH** to improve its indigenous capacity for cost effective vaccine production in Pakistan.
- **EPI** should devise mechanism and lead implementation plan for vaccine management, upgrade its capacity and plug various gaps after need assessment to timely deliver vaccines to national provincial and district levels.