EDITORIAL

How to Achieve Indigenous Self-sufficiency in Vaccine Development? A Roadmap

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For every nation state with a large population (Pakistan being the 5th largest), it is imperative to have indigenous capability to meet one's own requirement of vaccines for one's own set of prevailing diseases. Imports are costly and not always readily available as became evident globally during the ongoing COVID-19 pandemic. Microbial antigenicity may also vary significantly from region to region on account of mutations. Hence efficiency of vaccine too can vary accordingly.

Vaccines have dramatically reduced the burden of numerous infectious diseases, promoted individual and social growth, prosperity and wellbeing across the globe. In the coming decade, vaccines are likely to save twenty-five million lives[1], and will continue to be the cornerstone of public health programmes. It is estimated that six out of every ten infectious diseases in humans are transmitted by animals and 70% of emerging and re-emerging diseases are either spread from animals to humans or infected animals to the healthy ones through insects.[2] The role of vaccines in human health is therefore not only limited to humans but is vital to control disease transmission from animals to humans as well.

The availability of vaccines to address unmet and emerging infectious diseases remains a challenge, especially in underdeveloped and resource constrained countries. There is a dire need for the development of the required technical and scientific skill set, sufficient and sustained investment, as well as a framework that incentivizes and rewards research and innovation in this area. Recognizing the strategic, social and economic value of vaccine production, many governments in emerging countries, including China, India, Vietnam, Indonesia, Thailand, South Africa, Brazil, Mexico, Argentina are investing heavily in promoting domestic vaccine research, development and production.

Pakistan is still lagging behind significantly in the global vaccine development and production sector. With its rapidly growing population, the risks of emerging and reemerging infections and the ever present threat of bioterrorism, a concerted and coordinated effort is warranted for capacity building in this area. A system for vaccine development and production in the country requires the urgent implementation of “triple helix” model of government-academia-industry collaboration. The role of each entity should be clearly defined so that work can proceed in a coordinated manner.

The primary role of the Government is to facilitate academia and industry in their respective roles by developing policies that promote and incentivize R&D and entrepreneurship activities. Tax holidays and buy back guarantees should be offered to the industry to encourage them to invest in vaccine production while the bureaucratic processes related to procurement and business ventures should be simplified. Mapping of competency profiles of different universities, hospitals/clinical trial centers and industries involved in vaccinology based research should be conducted to provide a common platform for collaboration and interaction. Investment in vaccine production would be futile in the face of refusal by the public to use vaccines. The government needs to take concrete steps to counter vaccine hesitancy by conducting awareness programmes and confidence building measures involving all stakeholders including social and behavioural scientists, communications specialists and public health professionals and the general public.

The academia has to commit to quality basic and applied research that delivers an end product that can be brought to the market. Too many research projects end with the publication of the required research paper and do not translate into any benefit for our society. Industrial partnerships between the academia and industry are vital. Capacity building in vaccine research as well as significant investment in laboratory infrastructure with the capability for in silico, in vitro and in vivo research is required. Priority areas in vaccine development need to be identified basing on a critical assessment of public health needs. The establishment of Good Manufacturing Practices (GMP) platforms for vaccine manufacture for testing in phase I and phase II trials is needed.

For vaccines to reach the market, it is imperative to conduct high quality clinical trials according to international best practices. For this, it is necessary to train our clinical researchers in the requisite ethical and regulatory knowledge. Clinical trial centers/hospitals with the methodological competences to perform clinical studies

with standardized immune-monitoring, imaging, laboratory testing, and functional monitoring of physiological parameters should be established. In addition, capacity building of regulatory bodies for clinical trial authorization, policy making and review of licensure applications needs to be carried out.

The academia and industry need to work together to create effective partnership models in vaccine production. It is imperative that the private sector recognizes the role that university-led research and development can play in providing innovative solutions in vaccine production. Industry should invest in facilities that are capable of undertaking pilot projects related to vaccines that meet Good Laboratory Practices and current Good Manufacturing Practices standards and also commit to establishing bulk manufacturing plants for vaccines that comply with best international GMP standards.

There are no shortcuts on the way to self-reliance in vaccine development and production. All entities, the government, academia, regulatory bodies and industry need to be prepared to commit themselves to this process for the long haul, before self-sustenance can be achieved.

Editor-in-Chief

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