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55 Indian companies can make mRNA vax: Report

Rupali Mukherjee / TNN / Updated: Dec 18, 2021, 13:36 IST

MUMBAI: With the emergence of the highly-transmissible Omicron variant and an urgent need for boosters and more efficacious jabs, a global report for the first time has identified over 55 domestic companies including Biocon, Dr Reddy's, Sun Pharma, Reliance LifeSciences, Zydus Cadila, Intas and Lupin, which could potentially manufacture the messenger or mRNA vaccines.

The report by AccessIBSA and Médecins Sans Frontières (MSF), stresses the need to diversify and expand manufacture of mRNA vaccines to accelerate the roll-out of billions of doses possibly within six months, importantly, under a license from the originator companies-- Pfizer/BioNtech and Moderna. At present, mRNA vaccines manufactured by Pfizer and Moderna continue to be in short supply globally, and out of reach of several developing countries, including India.

This assumes significance at a time when the existing vaccines may need to be strengthened with booster shots, with several experts including Niti Aayog, member- health, VK Paul recently highlighting the need to tweak technology platforms in the wake of changing nature of the variant.

The list debunks the argument of innovators that there are no facilities globally, mainly outside the US and Europe, which have the capability to make these `complex' vaccines.

The mRNA technology is the preferred vaccine platform as it is simpler, quicker and easier to transfer as against older (pre-2020) vaccine technologies which are cell-based, Achal Prabhala co-author and coordinator of the AccessIBSA, which campaigns for access to medicines in India, Brazil, and South Africa, told TOI. The mRNA vaccines are made through biochemical rather than biological processes, which can be modified quickly and scaled up to target virus mutation.

In total, the report has identified over 100 companies in Africa, Asia, and Latin America with the potential to produce mRNA vaccines. It is important to note that this list represents a baseline scan, with a focus on technical feasibility. Recent research into requirements for mRNA vaccine manufacturing from MSF and Imperial College of London reveals that any pharmaceutical company currently manufacturing sterile injectables or injectable drugs satisfies the minimum criterion to manufacture an mRNA vaccine.

`The Indian government should play a proactive role, and urge the US and Germany to press their vaccine makers to share technology with companies here. It should also incentivise these domestic companies, who can kickstart the production of mRNA vaccines quickly'', Prabhala stated.

The investments estimated by MSF and Imperial College are between $127 million and $270 million, to produce 100 million vaccine doses. While the companies on the list are exporting sterile injectables to the European Union or US, or have been evaluated by the World Health Organization, which means that their plants are certified as meeting the gold-standard quality requirements.

But there are multiple factors to take into account, such as the ability to access the required investment, the strength of the drug regulatory authority in the country of manufacture, and, finally, the prospect of a strong business case.

Regarding the TRIPs waiver which may help in removing barriers for a diverse and global production of `innovator' vaccines, he said, it works completely with diagnostic tests and small molecule drugs, like the antiviral pills that will soon come to market. For vaccines, we absolutely need licensing and technology transfer from the originator companies, with or without a TRIPs waiver''.

Advocating the technology, the report says ''Unlike older (pre-2020) vaccine technologies which are cell-based, mRNA vaccines are made through biochemical rather than biological processes. This makes for a simpler system of production, and one that is more predictable and easier to transfer to other manufacturers than previous vaccine technologies. An essential consequence of the simplicity is speed: it takes three to seven days to produce a batch of the active pharmaceutical ingredient for the Pfizer/BioNtech vaccine, as compared to one month for an equivalent batch of the AstraZeneca vaccine. Also, the existing mRNA vaccines – Moderna and Pfizer/BioNtech – work against the variants we have witnessed before Omicron''.

If a company in Spain such as Rovi, that produces sterile injectables, with no experience making either biologic drugs or vaccines, can make Moderna's vaccine, then there is no reason why a company with a similar profile based in Morocco, South Africa, Brazil, India or Bangladesh, cannot do the same – should it receive a full technology transfer from Moderna, as Rovi did, the report points out.