

COVAXIN Approval : Need for Recognition

By **Abhinav Mehrotra & Dr. Biswanath Gupta** - August 2, 2021

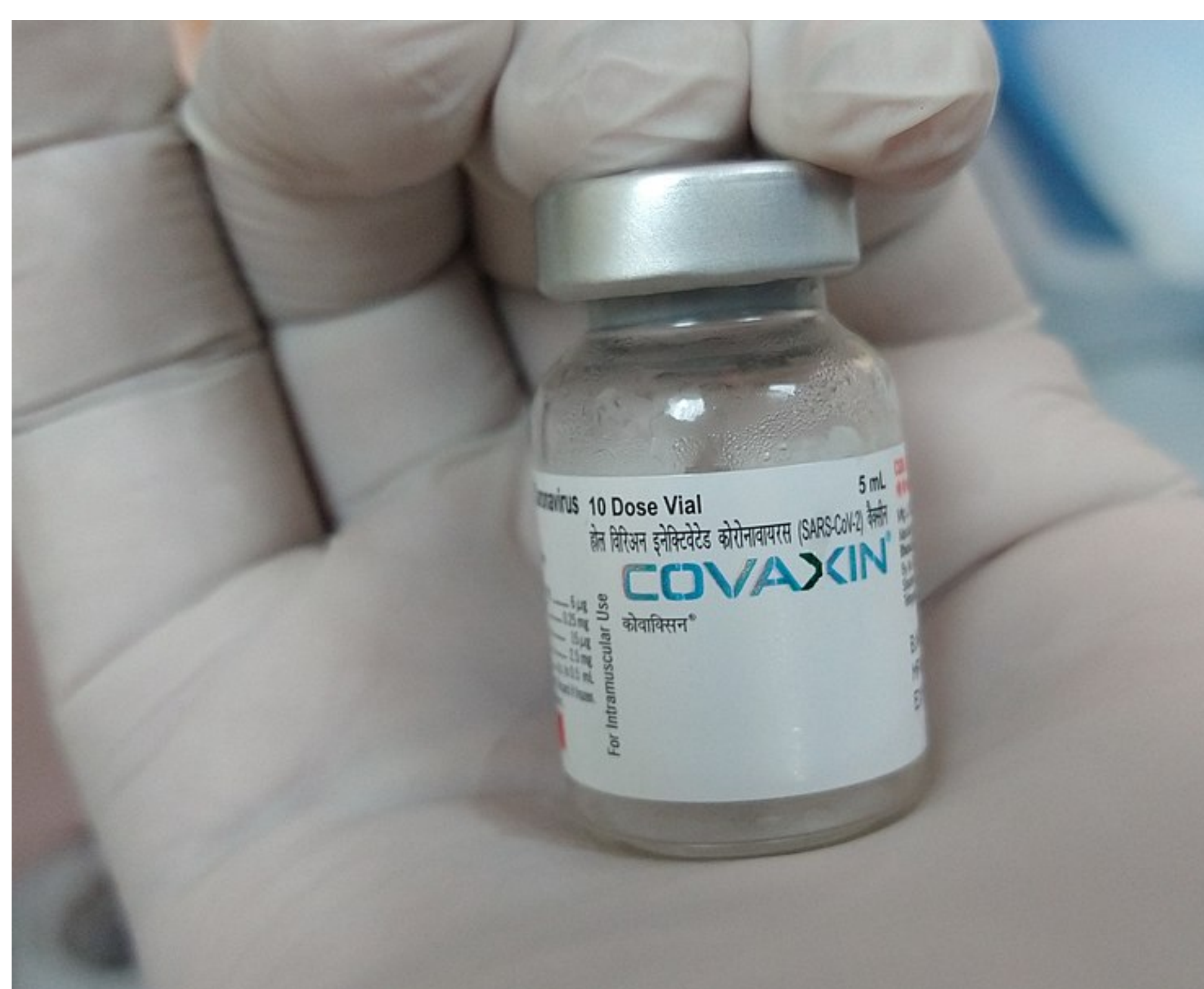


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Although it is expected that the COVAXIN will get **recognized** by end of August, what needs to be understood is the repercussion faced till now and possible pitfalls in case there is further delay. It need not be overemphasized that the impact of non-registration is directly linked with travelling abroad for various reasons. The core of the issue is the emergence of vaccine passport that may become a reality in the coming times. In practice, the purpose of the vaccine passports are to restart international travel, and reinvigorate the economy by certifying “safe” people and rapidly isolating those who are infected.

Though many countries are opposing it due to non-availability of vaccines, but the developed nations continue to impose certain listed vaccines as being compulsory to enter into their country as listed under the emergency use listing (EUL) of WHO. However, COVAXIN and Sputnik V that are being used in India do not find a place under the EUL so far. What needs to be taken note of are the **significant costs** that come with vaccine not getting recognized such as *job loss, banishment from campus, or deportation* that is likely to create inequalities and exacerbate discrimination.

In simple terms, the process for approval of a vaccine by WHO consists of **four steps**: an acceptance of the *manufacturer’s expression of interest* (EOI), a *pre-submission meeting* between WHO and the manufacturer, *acceptance of the dossier* for review by WHO, decision on *status of assessment*, and the *final decision on approval*. In case of Bharat Biotech’s Covaxin, although it has cleared the first three stages, there remains an uncertainty regarding it being recognized. All these efforts are significant because by being recognized under WHO’s emergency listing, it will give Covaxin international recognition which is significant given the fact that the European Union (EU), United kingdom (UK) and Canada have not included COVAXIN in their approved list of vaccines.

Coming to India, since the beginning of the vaccination program, India has been using two vaccines and the recent addition being Sputnik V produced by Gamaleya Research Institute of Epidemiology. While Covishield is manufactured by the Serum Institute of India in association with AstraZeneca and University of Oxford, Covaxin is a wholly indigenous vaccine developed by Hyderabad-based Bharat Biotech.

In this context, the people are trying to get Covshield jabs as it is the only recognized vaccine by WHO that is being used in India. This has created a lot of debate in India regarding the feasibility of vaccine passports. It was predicted by many scholars across the world that, people’s movement in the rich countries will be highly dominated by vaccine certificate. Like those who travelled abroad from India in the 1990s, they may remember that necessity of polio vaccine certificates for third world countries were necessary for travelling across Europe.

These kinds of restriction are not objectionable by law. As all the countries have all the right to protect their nationals from coronavirus catastrophe. Once the vaccination started in India, due to non availability of vaccine, people had no choice over which kind of vaccine to get inoculated with either they were administered Covishield or Covaxin. The core of the issue is that the Government of India still not able to list it in emergency list under WHO. This is one of the biggest diplomatic failures. The Indians who are travelling abroad or going for job/higher studies are facing challenges for taking covaxin vaccine in India. So far, only Iran, Philippines, Mauritius, Mexico, Nepal, Guyana, Paraguay and Zimbabwe have approved the Covaxin. Cut to the present, it is the Indian students who need to join the fall academic session in European countries, or job aspirants who need to travel to the United States, who are deeply affected that poses a huge dilemma in front of these students as well as may pose health risks.

Coming to Indian government’s response, it has distanced itself by stating that each country has its own regulatory system which is also the case in the case of Covaxin that is approved under the municipal system. However, the government in India has expedited the travel plans concerning educational purposes, for employment or who are on India’s official contingent to the Tokyo Olympic Games by shortening the gap to 28 days from the earlier prescribed 84 days for the second dose of Covishield vaccine. This sort of urgency is required in getting the Covaxin approved under the EUL under the WHO.

The views and opinions expressed in this article are those of the authors.

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