WHO GETS THE VACCINE?

While framing the rules, the government has to keep in mind that health is a fundamental human right, which has as its prerequisites social justice and equality. It should be accessible to all. Legal provisions are in place

By Dr KK Aggarwal

WHILE hearing a PIL, the Allahabad High Court on November 23, 2020, directed the central government to set up a meeting with the Indian Council of Medical Research (ICMR) through videoconference to verify whether the Covid-19 vaccine was being administered in other countries. A division bench of Justices Siddhartha Varma and Ajit Kumar noted: "...a general complaint amongst the members of the Bar is that though the vaccine is being administered in other countries but somehow it is not being administered in our country..."

The next day, an official of ICMR appeared before the High Court and provided information regarding the development of the vaccination programme in India and stated that the Covid-19 vaccine would be available in the near future.

Already, the prospect of a vaccine has spread across the globe after Pfizer, Moderna and now AstraZeneca have released encouraging results. In China, the government had given vaccine-maker Sinovac emergency approval for limited use in July. The company now plans worldwide distribution of the vaccine in early 2021—including in the United States. Another Chinese company Sinopharm's trials showed that the vaccine produced antibodies in volunteers, some of whom experienced fever and other side effects. The phase three trials took place in the United Arab Emirates (UAE) in July and in Peru and Morocco the following month. The government gave its approval to inject hundreds of thousands of people with its two experimental vaccines.

On September 14, the UAE gave emergency approval for the use of Sinopharm's vaccine on healthcare workers before Sinopharm shared data indicating it was safe and effective. Sinopharm also began testing a second inactivated virus vaccine with the Beijing Institute of Biological Products. After running early clinical trials in China, it launched phase three trials in the UAE and Argentina. The governments gave their approvals to inject hundreds of thousands of people with the two experimental vaccines.

In Russia, the Gamaleya Research Institute, part of Russia's ministry of health, launched clinical trials in June of a vaccine they called Gam-COVID-Vac. It is a combination of two adenoviruses, Ad5 and Ad26, both engineered with a coronavirus gene. In August, the Russian healthcare regulator approved the vaccine, re-named Sputnik V, before phase three trials had even begun. Negotiated agreements are on to supply the vaccine to other countries, including Brazil, Mexico and India.

In India, the Union health ministry says that a vaccine could complete its final trials in a month or two, raising hopes for a rapid roll-out in a country with the world's second highest number of infections. The ICMR and Bharat Biotech this month started the phase three trials of Covaxin in a process that will involve 26,000 volunteers. It is the most advanced Indian experimental vaccine. "We are in the process of developing our indigenous vaccines, in the process of completing our third-phase trials in the next one or two months," said Union Health Minister Dr Harsh Vardhan at a web conference on the pandemic. He reiterated the government's plan to immunise 200 million to 250 million Indians by July 2021. Vardhan, however, had said in September 2020 that the government could opt for emergency vaccine authorisation, particularly for the elderly and people employed in high-risk workplaces.

Indian officials have said they expect to rely on Covaxin and four other locally-tested vaccine candidates to control Covid-19, as they do not expect early access to sufficient quantities of those developed by Pfizer and Moderna. The other experimental vaccines on trial in India are the one being developed by AstraZeneca and Oxford University that is being manufactured by the Serum Institute of India; Russia's Sputnik-V; Zydus Cadila's ZyCoV-D, and one that Biological E Ltd is developing with Baylor College of Medicine and Dynavax Technologies Corp.

The PMO-constituted Vaccine Task Force will decide on the emergency use of the vaccine. The National Expert Group on Vaccine Administration for Covid-19 will lay down rules for the pricing.

NEED FOR A BLUEPRINT
Prime Minister Narendra Modi interacting with chief ministers regarding smooth administering of the Covid-19 vaccine in India

The central government is exploring the modalities of emergency authorisation and usage of coronavirus vaccines pending completion of phase three clinical trials and regular licensure. The PMO-constituted Vaccine Task Force will lay down the principles for emergency use authorisation. The National Expert Group on Vaccine Administration for Covid-19 will lead in setting the principles for advance market commitment, including vaccine pricing.

On November 20, PM Narendra Modi chaired a meeting of experts on ⇨

More tests are needed before the Serum Institute of India gets an approval for Covishield vaccine (above, left). Russia's Sputnik V vaccine (above, middle) has reported an efficacy of over 95 percent. Bharat Biotech's Covaxin (above, right) will soon begin its phase three trials in India. Pfizer (extreme left) and AstraZeneca have released encouraging results of the Covid-19 vaccines developed by them.

procurement and delivery strategy of Covid-19 vaccines. He wanted a time-bound plan for speedy regulatory clearances and timely procurement for early roll-out of the vaccination drive.

Legally, the existing legal framework is sufficient and rules are in place for the emergency authorisation of vaccines in India. The Epidemic Diseases Act, 1897, gives power to the states to take any measure to prevent an epidemic. It can be used for vaccines as well. The National Disaster Management Act, 2005, was widely used during the 68-day nationwide lockdown and in Covid-19-related containment zones. The Act can also come in handy to roll out vaccines. The centre is also armed with the New Drugs and Clinical Trial Rules, 2019, which mention "special situations for a new drug where relaxation, abbreviations, omission, or deferment of data may be considered", said another official.

The Indian government is still in the process of framing the rules and procedures for the administration of emergency authorisation of Covid-19. While framing the rules, the government has to keep in mind that the right to health is a fundamental right of all citizens of the country irrespective of caste, creed, gender, religion, health condition, etc. The right to adequate healthcare flows from the sanctity of human life and the dignity that belongs to all persons. Health is a fundamental human right, which has as its prerequisites social justice and equality. It should be accessible to all.

Right to health is not simply the right not to be unwell, but rather the right to be well. It encompasses not just the absence of disease or infirmity, but "complete physical, mental and social well-being", and includes both freedoms such as the right to control one's health and body and to be free from interference (for instance, from non-consensual medical treatment and experimentation) and entitlements such as the right to a system of healthcare that gives everyone an equal opportunity to enjoy the highest attainable level of health.

If the government administers vaccines by invoking the provisions of the Epidemic Diseases Act and the Disaster Management Act, it means that it has taken upon itself an obligation and the responsibility under Article 47, as a part of the guarantee under Article 21 of the Constitution to save and protect the lives of the public at large from the Covid-19 outbreak. To prevent the spread of any disease is the obligation or duty of the State under Article 47 of the Constitution. If the government administers the vaccine only to healthcare professionals and senior citizens, it would amount to failure to discharge the constitutional obligation under Article 47 and Article 21 of the Constitution. ■

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