Ministry of Health and Family Welfare

Safety and Efficacy of COVID-19 Vaccines

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As per New Drugs and Clinical Trials Rules, 2019 (ND & CT Rules 2019) under Drugs and Cosmetics Act, 1940 and in light of urgent need due to COVID pandemic in the country, Central Drugs Standard Control Organisation (CDSCO) in consultation with Subject Expert Committee (SEC) has granted permission to manufacture the following COVID-19 vaccines.

Covaxin vaccine is being manufactured by M/s Bharat Biotech International Limited. The firm had submitted interim safety and immunogenicity data of Phase I and II clinical trials carried out in the country along with safety data including Serious Adverse Event (SAE) data of the ongoing Phase III clinical trial in the country. The data was reviewed by Central Drugs Standard Control Organisation (CDSCO) in consultation with Subject Expert Committee (SEC) comprising domain knowledge experts. The committee noted that this vaccine is Inactivated Whole Virion Corona Virus Vaccine having potential to target mutated corona virus strains. The data demonstrated a strong immune response (both antibody as well as T cell) and in-vitro viral neutralization. The ongoing clinical trial is a large trial on 25800 Indian subjects in which all 25800 subjects have already been enrolled. Moreover, the firm presented the safety and efficacy data from Non-human primate challenge study also to CDSCO, where the vaccine has been found to be safe and effective.

After detailed deliberations, the SEC recommended grant of permission for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode, to have more options for vaccinations, especially in case of infection by mutant strains.

Based on the recommendations of SEC, CDSCO has granted permission to M/s Bharat Biotech International Limited, Hyderabad to manufacture Covaxin vaccine for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode with various conditions/restrictions.

M/s Serum Institute of India Pvt., Ltd. Pune has submitted safety immunogenicity & efficacy data of phase II/III clinical trials of AstraZeneca vaccine carried out in UK, Brazil and South Africa along with the safety & immunogenicity data from the ongoing Phase II/III clinical trial in the country. The Subject Expert Committee (SEC) of CDSCO reviewed the proposal of restricted emergency use along with above details and the data received. The Medicines and Healthcare products Regulatory Agency (MHRA) approval for AstraZeneca vaccine on 30.12.2020 along with its conditions/restrictions was also reviewed by the committee.

The committee noted that the safety & immunogenicity data presented by the firm from the Indian study is comparable with that of the overseas clinical trial data.

Based on the recommendations of SEC, CDSCO granted permission to Serum Institute of India to manufacture COVISHIELD vaccine for restricted use in emergency situation with various conditions/restrictions.

The Minister of State (Health and Family Welfare), Sh. Ashwini Kumar Choubey stated this in a written reply in the Rajya Sabha here today.

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MV/SJ
HFW /9th March2021/