Ministry of Health and Family Welfare

National Regulator approves “Conditional Market Authorization” of two COVID19 Vaccines- Covaxin and Covishield

Market Authorization conditional to submission of ongoing clinical trial data and safety data of the vaccine, at longer time intervals

All vaccinations to be recorded on CoWIN platform and AEFI, AESI to be strictly monitored

Approval reflects India’s proactive and agile COVID19 Management

Posted On: 27 JAN 2022 4:17PM by PIB Delhi

The National Regulator, Drugs Controller General of India (DCGI), has given nod to market authorization of two COVID19 vaccines, Covaxin and Covishield subject to certain conditions, here today. The Subject Expert Committee (SEC) of the Central Drugs Standard Control Organization (CDSCO) had recommended for upgradation of status for the vaccines from restricted use in emergency situations to grant of new drug permission with conditions in the adult population on 19th January 2022.

The market authorization of two COVID19 vaccines, Covaxin and Covishield, in the country by DCGI is subject to the following conditions:

1. Firm shall submit data of overseas ongoing clinical trials of the product with due analysis on six monthly basis or as and when available, whichever is earlier.

2. The vaccine shall be supplied for programmatic setting and all vaccinations done within the country to be recorded on CoWIN platform and Adverse Event Following Immunization [AEFI], Adverse Event of Special Interest [AESI] shall continue to be monitored. The firm shall submit the safety data including AEFI and AESI with due analysis on six monthly basis or as and when available, whichever is earlier as per NDCT Rules, 2019.

The proactive and agile approach followed by Government of India has been a hallmark of its strategy of management of COVID19. The latest approval accorded by DCGI for conditional market authorization to two COVID19 vaccines in the country indicates the promptness and timeliness with which the public response

strategy and decision making apparatus of the country has responded to the emerging needs during the pandemic.

It may be noted that of the global Stringent Regulatory Authorities, only the United States Food and Drug Administration (USFDA) Medicines and Healthcare products Regulatory Agency (MHRA) of the UK have granted "conditional market authorization" to Pfizer and AstraZeneca, respectively, for their COVID19 Vaccines.

"Conditional Market Authorization" is a new category of market authorization that has emerged during the current global pandemic of COVID19. The approval pathways through this route are fast-tracked with certain conditions to enhance the access to certain pharmaceuticals for meeting the emerging needs of drugs or vaccines.

India's nation-wide COVID19 vaccination program was launched on 16th January, 2021. As of today, more than 160 crore doses have been administered. The Union Government is committed to accelerating the pace and expanding the scope of COVID-19 vaccination throughout the country. New categories of population have been added to the national COVID19 vaccination drive starting from 3rd January 2022.

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MV/AL

HFW/DCGI market authorization/27th January 2022/4

(Release ID: 1792956)