US FDA ALLOWS “Remdesivir” antiviral drug for severely ill COVID 19 patients

Part of: GS-III- S&T (PT-MAINS-PERSONALITY TEST)

In United States, the Food and Drug regulatory body FDA has allowed emergency use of the antiviral drug, Remdesivir for treatment of severely ill COVID19 patients. A study by Gilead Sciences in US has shown that Remdesivir shortens the recovery time by 31 percent or about four days on average, for hospitalized COVID-19 patients.

According to reports, a clinical trial of Remdesivir was conducted on 1,063 patients. Those given the drug were able to leave the hospital in 11 days on average versus 15 days for the comparison group. US National Institutes of Health Director, Anthony Fauci said the drug would become a new standard of care for severely ill COVID-19 patients like those in this study.

About USFDA

The Food and Drug Administration (FDA or USFDA) is a federal agency of the United States Department of Health and Human Services, one of the United States federal executive departments.

- The FDA is responsible for protecting and promoting public health through the control and supervision of the safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceuticals (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed and veterinary products.
- The FDA was empowered by the United States Congress to enforce the Federal Food, Drug, and Cosmetic Act, which serves as the primary focus for the Agency;
- The FDA also enforces other laws, notably Section 361 of the Public Health Service Act and associated regulations, many of which are not directly related to food or drugs.
- These include regulating lasers, cellular phones, condoms and control of disease on products ranging from certain household pets to sperm donation for assisted reproduction.

The FDA is led by the Commissioner of Food and Drugs, appointed by the President with the advice and consent of the Senate. The Commissioner reports to the Secretary of Health and Human Services.

What is the FDA equivalent in India?

The Central Drugs Standard Control Organization is the Indian regulatory body for pharmaceuticals and medical devices, being the equivalent of the FDA in the US.

CDSCO

The Central Drugs Standard Control Organisation (CDSCO) under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the National Regulatory Authority (NRA) of India.

Functions: Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of New Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organizations by providing expert advice with a view to bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.
CDSCO along with state regulators, is jointly responsible for grant of licenses of certain special categories of critical Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera.