Covid-19 and the Orphan Drug Act

Why in News

Recently, the **World Health Organisation (WHO)** declared the **Covid-19 outbreak a pandemic.** However, **the United States Food and Drug Administration (FDA) declared Covid-19 an orphan disease,** or a **rare disease.**

Key Points

- The FDA granted Gilead Sciences **orphan drug status** for its antiviral drug, **Remdesivir,** on March 23, 2020.
  Originally developed to treat Ebola, the drug is now being tested for treating COVID-19. Clinical trials are already in Phase III.
- But on March 25 Gilead announced that it had submitted a request to the FDA to remove its orphan drug designation for Remdesivir.
  - Earlier, Gilead had sought the orphan status to the Remdesivir drug to expedite approval of the drug. However, advocates for global access to medicines, rejected the company's argument.
  - Gilead's exorbitant pricing of its drug to treat hepatitis C and its drug to treat HIV also attracted attention in the past.
- In recent years, drug companies have been accused of exploiting the law to reap profits, in sales.

Orphan Drug Act, 1983

- **Rare diseases became known as orphan diseases** because drug companies were not interested in adopting them to develop treatments.
- In the U.S., under the Orphan Drug Act, **companies are provided incentives to develop therapies, or orphan drugs,** for rare diseases.

- The Act allows **seven years of market exclusivity** and financial incentives **to innovators of these drugs.** As a result, orphan drugs are **often exorbitantly priced.**
- Privileges under the Act may be conferred to companies for drugs **to treat a disease that affect less than 200,000 people in the U.S., or for a disease that affects more than 200,000 people but for which there is no hope of recovering R & D costs.**
    The idea is that without these incentives, companies would find it difficult to recover their R&D costs given the small number of people suffering from the rare disease.

Issues

- **Covid-19 not a Rare Disease:** The Orphan Drug Act applies to a potential drug for COVID-19, which is anything but a rare disease, with 800,049 confirmed cases across the world.
- **Paradox:** The U.S. FDA conferred the status of an orphan drug on Remdesivir proposed to treat COVID-19 a pandemic.

Impact

- Had Gilead not sought that orphan drug status be rescinded, **generic manufacturers would not have been able to market a drug to treat COVID-19 with the same active ingredient till the seven-year period of market exclusivity** had ended.
- This would have given Gilead **free rein on pricing and licensing** which would have had **disastrous consequences on the healthcare system.**
- However, **orphan drug status of Remdesivir would have no impact on India** as Gilead Sciences holds patents in India and patents are open to challenge.
- As far as its patent rights are concerned, **Indian law permits the government to issue a compulsory licence in certain circumstances** of a public health crisis under **Section 92 of the Patents Act.**
    This would allow third parties to manufacture a patented drug without permission of the patent holder.

Rare Diseases

- A rare disease is a health condition of low prevalence that affects a **small number of people** compared with other prevalent diseases in the general population.
    There is **no universally accepted definition** of rare diseases and the definitions usually vary across different countries.
- Though rare diseases are of low prevalence and individually rare, collectively they affect a considerable proportion of the population.

- 80% of rare diseases are **genetic in origin and hence disproportionately impact children.**
- In India there are **56-72 million people affected by rare diseases.**
- There is also a demand for the **reformulation of National Policy for Treatment of Rare Diseases, 2017.**

National Policy for Treatment of Rare Diseases, 2017

- The policy highlights the measures and steps, both in the short as well as in the long term, that need to be taken to deal comprehensively with rare diseases.
- The policy intends to constitute an Inter-ministerial Consultative Committee to coordinate and steer the initiatives of different ministries and departments on rare diseases.
- It also mentions the creation of a corpus fund at Central and State level for funding treatment of rare diseases.
- The policy aims to create a patient registry for diseases housed in **Indian Council of Medical Research (ICMR).**
- However, recognizing the higher cost of treatment for rare diseases, the policy also seeks to strike a balance between access to treatment and health system sustainability.
- It also aims to create awareness among health professionals, families of patients and the public in general, about rare diseases.

Source: TH