Covid-19 and the Orphan Drug Act – Rare diseases

Part of: GS Prelims and GS-III- S&T

- 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

  - 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- Had Gilead not sought that orphan drug status be rescinded, generic manufacturers would not have been able to market a drug to treat COVID-19 with the same active ingredient till the seven-year period of market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.

### 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, to deal comprehensively with rare diseases.
- The policy intends to constitute an Inter-ministerial Consultative Committee to coordinate and steer 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, under Section 92 of the Patents Act.
- 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.

### 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.

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