

5. COVID-19 and the Orphan Drug Act

Prelims Syllabus: Medicine and Pharmaceuticals

Mains Syllabus: GS-II Issues relating to development and management of Social Sector or Services relating to Health, Education, Human Resources.

Why in News?

- Despite the World Health Organisation (WHO) recently declared the Covid-19 outbreak a pandemic, the United States Food and Drug Administration (FDA) declared COVID-19 an Orphan Disease, or a Rare Disease.

Key Points Regarding the Issue:

- 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.

What is a Rare Disease?

- 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.

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- There is also a demand for the reformulation of National Policy for Treatment of Rare Diseases, 2017.

About 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.

About 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.

Issues Regarding the Declaration:

- **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.

Impacts on declaring as Orphan Disease:

- Had Gilead not sought that orphan drug status be repealed, 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.

