Custom Exemption on Drugs for Rare Diseases

Why in news?

Recently, custom duty was removed on drugs for rare diseases and on cancer immunotherapy medicine (Keytruda) providing financial relief to people with rare diseases.

What are rare diseases?

- According to the ***World Health Organization (WHO***), a rare disease is a *debilitating lifelong disease or disorder* with a prevalence of *10 or less per 10,000 population*.
- Treatment of rare diseases can be very expensive going up to Rs 1 crore per year.
- There are about *7,000 to 8,000 conditions* globally that have been defined as rare diseases.
- The ***National Organization for Rare Disorders (NPRD)*** estimates that for a child weighing 10 kg, the annual cost of treatment for some rare diseases may vary from Rs 10 lakh to more than Rs 1 crore per year.

What is status of rare diseases in India?

- 4,001 rare disease cases were recorded as of 2021.
- The most common rare diseases in India

Diseases	Impacts
• Primary immunodeficiency disorder	• A genetic condition that impairs the immune system
• Lysosomal storage disorders	• A group of metabolic disorders that lead to a buildup of toxic materials in the cells
• Small molecule inborn errors of metabolism	• A large group of genetic conditions where the genetic code for metabolic enzymes are defective
• Cystic fibrosis	• A condition that severely damages the lung leading to the need for a transplant
• Osteogenesis imperfect	• A condition where bones fracture easily

What initiatives were taken for rare diseases?

- **Custom duty** -Medicines and foods needed for the management of 51 rare diseases have been exempt from custom duty.

National policy for rare diseases (NPRD) 2021

- **Aim** - The NPRD 2021 has provisions for promotion of research and development for diagnosis and treatment of rare diseases.
- **Categorization** -The rare diseases have been identified and categorized - Group 1, Group 2 and Group 3.
    - **Group 1 category** - Disorders amenable to one-time curative treatment.
    - **Group 2 category** - Diseases requiring long term/lifelong treatment having relatively lower cost of treatment and benefit has been documented in literature and annual or more frequent surveillance is required.
    - **Group 3 category -** Diseases for which definitive treatment is available but challenges are to make optimal patient selection for benefit, very high cost and lifelong therapy.
- **Centres of Excellence (CoEs)** – 8 CoEs have been identified for diagnosis, prevention and treatment under National Policy for Rare Diseases 2021.
- **Financial support** - Up to Rs. 50 lakhs to the patients suffering from any category of the Rare Diseases and for treatment in any of the CoEs.
- **Nidan kendras** -Have been set up for genetic testing and counselling services.

Quick Facts

Keytruda

- Keytruda is mainly used in adults for cancers that are advanced, have spread or returned, are not responding to other treatments or cannot be removed by surgery.
- It is also used to help *prevent the cancer from coming back* after patients had surgery to remove melanoma or renal cell carcinoma (adjuvant therapy).
- The active substance in Keytruda is ***pembrolizumab***, a monoclonal antibody.

References

1. The Hindu Rare | Diseases
2. The Indian Express | Customs Duty

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