Custom Duty removal on drugs for Rare Disease

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Why is in news? The central government recently exempted all foods and drugs for rare diseases imported by people for personal use from custom duty. With most therapy for rare diseases priced very high, this will make a significant difference to families of people living with the conditions.

A Brief about Rare diseases

Rare diseases as the name suggests are conditions that affect very few people.

The World Health Organisation defines it as any debilitating lifelong disease or disorder with a prevalence of ten or less per 10,000 population; other countries follow standards ranging between 1 and 10 cases per 10,000 to define a condition as rare disease.

There are about 7,000 to 8,000 conditions globally that have been defined as rare diseases. The landscape of rare diseases keeps changing, with newer conditions being identified and reported constantly.

With limited experience of these diseases, they are extremely difficult to diagnose and more difficult to test for. A report quoted by the country's National Rare Disease Policy 2021 says that in the United States a person with a rare disease gets diagnosed on average after 7.6 years and in the United Kingdom after 5.6 years.

The patients have to visit as many as eight physicians, including four specialists, to get a diagnosis. Two to three misdiagnoses are also typical before getting the final diagnosis, as per the study.

Even after one gets a diagnosis, most of the rare diseases do not have a specific treatment. And, the ones that do can be prohibitively expensive.

Why are drugs for rare diseases so expensive?

Even though there have been developments in the treatment of rare diseases in the recent year, almost 95 per cent of the conditions do not have specific treatment.

With a very small number of people suffering each of the 7,000- 8,000 rare conditions, they do not make a good market for drugs.

This is the reason most pharmaceutical companies are reluctant to spend on research for treatments of the disease.

This is the reason the medicine for rare conditions that do exist are known as "orphan drugs" and are prohibitively priced to recoup the cost of research and development.

As per the National Rare Disease Policy, treatment for some rare disease can vary from Rs 10 lakh to 1 crore per year for a child weighing 10 kgs. The treatment has to be continued lifelong, with the costs going up along with the age and weight of the person.

The policy state that at present, very few pharmaceutical companies are manufacturing drugs for rare diseases globally and there are no domestic manufacturers in India,"

The situation in India

Data on how many people suffer from conditions that are considered to be rare diseases globally is not available in India.

There is no epidemiological data on the incidence, but cases reported from tertiary care hospitals do get recorded in the national portal that was set up by the Indian Council of Medical Research after the rare disease policy came out.

As per data submitted to the parliament in December 2021, at least 4,001 rare disease cases were recorded on the portal.

The most commonly reported rare disease includes

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), and certain forms of muscular dystrophies and spinal muscular atrophy.

A brief about Custom duty exemption

Medicines and foods needed for the management of 51 rare diseases have been exempt from custom duty, with the government notification stating, “drugs, medicines or food for special medical purposes used for treatment of rare diseases specified.”

The specified conditions include lysosomal storage disorder (a group of metabolic disorders that lead to a buildup of toxic materials in the cells), maple syrup urine disease (a hereditary condition where the body cannot process the building blocks of proteins resulting in buildup of harmful substances in blood and urine), Severe food protein allergy, Wilson’s disease (a disorder that results in the body accumulating copper) among others.

These medicines usually attract a basic custom duty of 10 per cent, with some vaccines or medicines attracting a lower 5 per cent or nil as previously notified.

Medicines for the treatment of spinal muscular athrophy and duchenne muscular dystrophy were already exempt from customs

This will be a huge relief for people living with rare diseases because many of the medicines and food products are not available in India and have to be imported.

The cost of the medicines is also usually very high, going up with the increasing age and weight of the person. And, the medicines for many of the conditions have to be taken for life.

Way to avail the benefits

To avail the benefits, people importing it have to get a certificate from the central director general, deputy director general, or assistant director general of health services, director general of state health services, or district medical officer or civil surgeon.

The certificate has to be provided to the deputy commissioner of customs or assistant commissioner of customs at the time of clearance. Or, the person will have to give an undertaking to furnish the certificate in a specified period, failing which the custom duty will have to be paid.

Other measures taken

Other than relief from custom duty, the government also has provision for providing financial support up to R50 lakh for the treatment of any kind of rare disease at the Centres of Excellence. Earlier, financial aid of up to R20 lakh was provided to those with Group 1 rare diseases where one-time curative treatments exist.

Other than that the Centres of Excellence would develop Standard Operating Protocols to be used at various levels of care for patients with rare diseases to improve early diagnosis, better care coordination and quality of life.