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## Extend GST Waiver To All Rare Diseases Drugs: Industry Body & Patient Groups Highlight Gaps

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by Shivam Tyagi

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In a welcome move on Tuesday, Nirmala Sitharaman, Union Minister for Finance and Corporate Affairs chairing the 50th Goods and Services Tax (GST) Council announced several exemptions and new taxes. Among the exemptions, a decision to exempt IGST (Integrated Goods and Services Tax) on the cancer drug dinutuximab (Qarziba) was taken when imported for personal use.

The drug dinutuximab beta is a second line of treatment for neuroblastoma, a cancer of nerve cells in patients over 1 year of age. The drug is manufactured by a UK-based pharmaceutical company EUSA Pharma and is imported into India costing patients around Rs 36 lakh.

Apart from this the council also exempted medicines and Food for Special Medical Purposes (FSMP) used in the treatment of rare diseases enlisted under the National Policy for Rare Diseases, 2021 when imported for personal use subject to existing conditions.

Similarly, the government said that the IGST exemption is also being extended to FSMP when imported by Centres of Excellence (COE) for Rare Diseases or any person or institution on the recommendation of any of the listed Centres of Excellence. Presently, there are eight Centre of Excellence in India which were established under the 2021 Rare Diseases Policy.

While The GST Council's decision was well received across the spectrum, pharmaceutical companies, industry bodies and patient advocacy groups have argued that the exemption should be applicable to all rare disease drugs and should not be only restricted when imported for personal use as this can pose multiple challenges for patients.

Ruchi Sogarwal, Director of Corporate Affairs, Takeda Biopharmaceuticals India called the decision a step in the right direction. However, Dr Sogarwal argued that all patients requiring treatment are not aware of and capable of navigating the process of importing drugs, obtaining an import licence, and undertaking administrative tasks. Hence, there is a limited benefit to this decision from the patient's perspective due to operational challenges.

"The NPRD identifies the Center of Excellence (apex Government hospitals) which provide treatment for all rare diseases in India. Hence, it would be much more beneficial to patients if the government extends the full IGST exemption for the import of drugs to all the Center of Excellence. We hope that the Government will consider the same in the near future since it is a much awaited relief for the patients," Sogarwal said.

Echoing the same sentiment Dr Ratna Devi, Director, Patient Academy for Innovation and Research told BW Healthcare World that patients do not have the knowledge or resources to manoeuvre the complex approvals process needed for personal imports. "Therefore, it is essential that these GST waivers be extended to encompass all approved rare disease treatments in India and not be restricted to personal imports. Additionally, the government should consider exemption on medicines for all groups of rare diseases to ease the financial burden on patients and their families," Dr Devi stated.

As per the 2021 rare disease policy document, there are around 7000 to 8000 rare diseases existing around the world today, of which therapeutic treatment is available for only 5 per cent of all the diseases. Rest 95 per cent of diseases have no approved treatment and less than 1 in 10 patients receive a disease-specific treatment. The pharmaceutical therapies available for the limited rare diseases today are prohibitively expensive making patients run from pillar to post to acquire the funds to treat these treatments.

The policy document also revealed 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 1 crore per year with treatment being lifelong and drug dose and cost, increasing with age and weight.

Presently under the government's policy, several rare diseases are divided into three groups which have monetary as well as non-monetary assistance provided to the patients by the government.

"Our expectation is that the government should give us support on treatment in a sustainable manner. We are struggling to access treatment because of inconsistent funding availability at COE level, we are hoping that the government should listen to our appeal and provide support which is much awaited," said Raja Murugappan, President, of Rare Diseases Support Society.

The official prevalence of rare diseases in India is unclear as there is no registry of the diseases at the government level, although unofficial industry estimates peg the case burden to be somewhere around 72 to 96 million people who suffer from these diseases.

Last year, a parliamentary panel had requested the government to waive the GST on cancer drugs and take strong measures to check the prices of medicines and radiation therapy, the media reported.

Spokespersons from the pharmaceutical industry body Organisation of Pharmaceutical Producers of India (OPPI) told BW Healthcare World, that the exemption will not be available to drugs which are commercially available in the market imported either by private entities or launched by global companies.

V Simpson Emmanuel, MD and CEO, Roche Pharma India and Co-Chair, Rare Disease Committee, OPPI pointed out that keeping patient interest in mind, companies are launching innovative treatment options in India at the earliest. "It helps patients avoid going through a complex process of importing every time they need it. All patients treated on a locally available, approved product are deprived of the customs duty and GST waiver benefit. Even CoEs cannot import such products and get the duty benefit for patients because if a product is registered and available in India, licence at a patient level or at an institute level is not allowed," Emmanuel said.

"At OPPI we would like to see such exemptions being extended not only to patients but also to medical institutions, and importers including private. Extending this exemption from customs duty to all would not only help patients financially but also make sure that these life-saving medicines are available to everyone who needs them, especially children with rare diseases. OPPI, therefore, believes that all life-saving drugs, be it Rare Diseases or cancer should be exempted from customs duty and GST," said Suresh Pattathil, President of OPPI.