

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**RAJYA SABHA
UNSTARRED QUESTION No. 598
TO BE ANSWERED ON 07th FEBRUARY, 2023**

AVAILABILITY OF MEDICINES TO TREAT RARE DISEASES

598. SHRI K.R.N. RAJESHKUMAR:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether it is a fact that, some important medicines to treat rare diseases, are not available in the country;
- (b) if so, the details of the medicines;
- (c) whether the Ministry has received any demand for medicines from Centre of Excellences;
- (d) if so, the details of the medicines and timeline for the medicine availability; and
- (e) if not, the reasons therefor?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY
WELFARE
(DR. BHARATI PRAVIN PAWAR)**

(a) & (b): A disease that occurs infrequently is generally considered a rare disease, and it has been defined by different countries in terms of prevalence, either in absolute terms or in terms of prevalence per 10,000 populations. A country defines a rare disease most appropriate in the context of its own population, health care system and resources.

In order to help the patients in terms of affordable medicines, Department of Pharmaceuticals has initiated the implementation of Production Linked Incentive Scheme for Pharmaceuticals. The Scheme provides for financial incentives to manufacturers selected under the Scheme for domestic manufacturing of various product categories, which also include Orphan drugs. The Guidelines for the Scheme are available on the website of the Department of Pharmaceuticals under the tab 'Schemes'.

There are some medicines for rare diseases which are imported from outside the country. These include Gene therapy medicines (e.g. for Spinal Muscular Atrophy); some of the enzyme replacement therapies for lysosomal storage disorders, Nusinersen for Spinal Muscular Atrophy etc.

(c) to (e): As per the provisions envisaged under Guidelines and Procedures issued on 11.08.2022, the Centre of Excellence demand fund for treatment of the patients suffering from various rare diseases from Ministry of Health and Family Welfare. 11 Centres of Excellence have been identified by Government of India for treatment of rare diseases.
