

**Recommendations of the SEC (Endocrinology & Metabolism) made in its 14<sup>th</sup> meeting held on 20.06.2025 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>SND Division</b>			
1.	SND/IMP/23/000069  Triptorelin Powder for Injection 22.5 mg	M/s. Dr. Reddy's Laboratories Limited	<p>The firm presented the proposal for grant of permission to Import and Marketing of Triptorelin Powder for Injection 22.5 mg for additional indication for the treatment of confirmed central precocious puberty in children aged 2 years and over with onset of CPP before age 8 in girls and age 9 in boys along with CT waiver request before the Committee.</p> <p>After detailed deliberation on 22/05/25 and subsequent discussion on 20/06/25, the Committee desired that firm should present more data in respect of followings:</p> <ol style="list-style-type: none"> <li>1) Clinical Studies, published reports on Indian Race population</li> <li>2) Unmet need of the drug for applied indication in Indian population</li> </ol>