

Recommendations of the SEC (Reproductive) made in its 10th/25 meeting held on 13.11.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/IMP/20/000082 Estradiol 1.53 mg/ actuation transdermal spray	M/s. Themis Medicare Limited	<p>The firm presented the PMS study report of Lenzetto (Estradiol 1.53 mg/actuation transdermal spray) in post-menopausal women.”</p> <p>The committee noted the following observations & asked the firm to submit and present the following points:</p> <ol style="list-style-type: none"> 1. The study was proposed for menopausal women; however, the results were presented only on Vasomotor symptoms. The firm has to show the subgroup data analysis with respect to the number of patients (natural, surgical and premature menopause), demographic details, including age, type of progestin used, route of administration and continuous or 14 days in patients with uterus and data of patients having withdrawal bleeding. 2. The latest terminology should replace Climacteric symptoms. 3. PMS was conducted/ completed in 394 patients but the analysis was based on 400 patients. 4. Data on safety profile monitoring parameters such as ultrasound of breast, uterus, and endometrial thickness, besides blood coagulation profile, Blood Pressure should be provided. 5. Data on improvement for the GSM, psychological symptoms like depression and mood changes and other post-menopausal symptoms to be explained in details. 6. Data on dose escalation in the 12 weeks’ study i.e., from 4th to 8th and 12th weeks, to be submitted. 7. The power of the study is to be explained.