

Recommendations of the SEC (Reproductive) made in its 10th meeting held on 05.11.2024 at CDSCO HQ New Delhi:-

Sr.no.	File Name & Drug Name, Strength	Firm name	Recommendations
1	SND/MA/23/000140 Dydrogesterone Modified Release Tablet 20mg	M/s. Abbott India Limited	<p>The firm presented the Phase III Clinical Trial Report of Dydrogesterone modified release tablet 20 mg on 05.11.2024.</p> <p>In light of earlier recommendation dated 25.05.2023 and discussion held with SEC experts on 05.11.2024 & 31.12.2024, Committee recommended for approval of manufacturing and marketing permission of Dydrogesterone Modified Release Tablets 20 mg in proposed indications subject to the condition that firm should conduct the Phase IV Clinical Trial in Indication: Threatened miscarriage & Habitual miscarriage and interim CT data on 25% patient population should be submitted to CDSCO within 09 months from the date of CT permission.</p> <p>Accordingly, firm should submit the Phase IV CT protocol to the CDSCO within 03 months from date of approval for further deliberation before SEC.</p> <p>The Committee also opined that other firms should also conduct the Phase IV Clinical Trial in Indications: Threatened miscarriage & Habitual miscarriage.</p>