Recommendations of the SEC (Urology) made in its 07th/25 meeting held on 21.08.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Devices Division			
1.	CI/MD/2025/145443 BPH Pulse Field Ablation Device	M/s Trialguna Private Limited	The firm presented proposal for grant of permission to conduct Pilot clinical investigation of medical device, i.e., BPH Pulse Field Ablation Device manufactured by M/s ALPFA Medical, USA, vide Clinical investigation plan number CS00001 dated 02/12/2024. The said device is intended to be used for the treatment of lower urinary tract symptoms associated with benign prostatic hyperplasia (BPH) in men above 45 years of age. The said device is not yet approved by any country. There is no clinical data generated on human subject. The proposed clinical study is a part of global study. The other countries involved in the said study are Italy and Czech Republic for generation of safety and feasibility of the medical device. After detailed deliberation, the committee opined the following: 1. The pre-clinical study data submitted by the firm was not adequate. 2. The firm should submit the clinical study data generated on the human subjects globally to prove safety and effectiveness of the said device. 3. Also, the said device is not yet approved by any of the National Regulatory Authorities, i.e. Country of Origin (USA) or other countries viz. EU, UK, etc. Therefore, the regulatory approval of the said medical device in the country of origin (USA) or other countries where the study is ongoing shall be submitted. 4. OECD certification of the lab where the preclinical study is carried out, need to be submitted, before taking necessary action in the matter.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
2.	SND-16011(11)/82/2025-eoffice Febuxostat Extended Release Tablets 40/80 mg	M/s. Akums Drugs & Pharmaceuticals Ltd.	Firm presented their proposal for grant of permission to manufacture and market Febuxostat Extended Release Tablets 40/80 mg for the treatment of chronic hyperuricemia in conditions where urate depression has already occurred (including a history, or presence of tophus and /or gouty arthritis) along with Phase III CT study report of Febuxostat Extended Release Tablets 40/80 mg. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Febuxostat Extended Release Tablets 40/80 mg for the proposed indication subject to condition that the firm should conduct Active PMS Study. Accordingly, the firm should submit Active PMS Study protocol to CDSCO within three months from date of approval of the drug.