Recommendations of the SEC (Dentistry) made in its 09th meeting held on 22.12.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/IMP/23/000041 Endomethasone N	M/s. Septodont	The firm didn`t turn up for presentation.
SND Division			
2.	SND/MA/21/000508 Metronidazole ER (Controlled Release) Tablets 600mg (Additional Indication)	M/s. Abbott Healthcare Private Limited	In light of earlier SEC recommendations dated 31.05.2023, the firm presented the pharmacokinetic study report of Metronidazole CR tablets 600mg before the committee. The committee noted that the PK study report submitted by firm to CDSCO and presented before committee is deficit with respect to the efficacy, safety and patient acceptance of the dose of the proposed drug i.e. 2 tablet of Metronidazole CR tablets 600mg (1200 mg dose of metronidazole once a day), procedure adopted with respect to adverse events reported and/or mentioned in the report along with evidences. Further, no safety data for use of 2gm of Metronidazole for 7 days could be shown by the firm. After detailed deliberation, the committee opined that the firm still not presented the data to support safety of their product's proposed dose of Metronidazole (2 x 600mg tablets OD for 5 days) along with complete comparative PK data. The committee recommended that the firm needs to submit complete pharmacokinetic study report of Metronidazole CR tablets 600mg along with supporting documents & the complete copy of literatures presented by the firm during the meeting, safety data for 2gm of Metronidazole once daily for 7 days and 1200mg efficacy/effective dose data for 24 hours. Further, committee noted that in the last meeting same points were raised, wherein it is well known that the use of 400 mg metronidazole causes gastric irritation and metallic taste in most individuals and

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			the study on use of 600 mg two tablets stat should be focused on these side effects rather than non-specific mention of adverse effects. The committee also desired to see the complete publication (in Journal) and the detailed report wherein the firm is claiming that safety profile was established on healthy volunteers. The clinical efficacy of metronidazole 400mg and 600 mg doses is almost equal, as per the study presented by the applicant. If clinical efficacy is the same and the conventional dose can be tolerated well, then the applicant should justify the additional indication of a 600 mg ER OD dose for oral infection. Further, firm should present scientific & authentic data on the uses of 2 tablets of 600mg OD dose, especially in relation to adverse effect (metallic taste & GI symptoms), and about the clinical efficacy as compared to 400 mg conventional dosing, at their next meeting. If they are unable to collect the same, they should conduct a trial on the efficacy of single versus conventional dosing and justify the additional indication of the Metronidazole 600 mg ER OD dose. The committee also opined that the applicant was unable to present any robust data on the usage of the 600mg ER OD dose in their multiple presentations since long, which shows that there is a research gap in the usage of the 600mg OD dose as compared to the 400 mg TDS dose. Accordingly, the committee recommended that the firm should submit clarification and data as above to CDSCO for further review by the committee to take final decision in the matter.