

Recommendations of the SEC (Endocrinology & Metabolism) made in its 18th/24 meeting held on 24.10.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	r-DNA11011(18)/95/2024-eoffice Agalsidase Alfa (REPLAGAL®)	M/s Takeda Biopharmaceuticals India Pvt. Ltd.	<p>In continuation to the earlier SEC meeting dated 13.08.2024, the firm presented the proposal for update in the package insert regarding home infusion and administration by the patient in presence of a responsible adult or administration by the patient's caregiver (self-administration) for patients who are tolerating their infusions well.</p> <p>The Committee noted that drug is indicated for the treatment of Enzyme replacement therapy for Fabry Disease and proposed changes in package insert are approved by EMA.</p> <p>After detailed deliberation, the committee recommended that the drug should preferably be administered by the treating physician in the clinical settings but incase of inability, drug can also be administered with the help of trained paramedical staff at home after obtaining consent from the patient and with the approval of treating physician only. Patient shall be informed through Informed Consent Form (ICF) for the risks involved in the administration of drug at home settings. ICF shall be obtained by the treating physician. ICF format with standard language shall be prepared by the MA holder who will provide the same to the treating physician.</p> <p>Accordingly, firm should submit the revised package insert to CDSCO for further evaluation.</p>
SND Division			
2.	SND/MA/23/00011 5 Metformin Hydrochloride Sustained-release Tablets 500mg/1000mg	M/s USV Pvt. Ltd.	<p>In light of earlier SEC recommendations dated 10.04.2024, the firm presented justification for waiving further animal studies based on available animal toxicity data and clinical data of Metformin covering teratogenicity for the safety of Metformin SR formulation before the committee along with gynaecologist & neonatologist (Special</p>

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			<p>Invitees).</p> <p>After detailed deliberation, the committee recommended for grant of permission to update the proposed statement in the prescribing information of Metformin Hydrochloride SR Tablets 500mg/1000mg i.e. “if clinically needed, the use of Metformin can be considered during pregnancy and in the periconceptional phase as an addition or an alternative to insulin” with condition to mention the additional statement i.e. “based on treating physician discretion”.</p>