

Recommendations of the SEC (Veterinary) made in its 12th/25 meeting held on 15.12.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Veterinary Division			
1.	F.No.Vet-11011(16)/01/2023-2102 Afoxolaner 11.3 mg/28.3/68/136 mg chewable tablets. For treatment of Dogs	M/s Boehringer-Ingelheim India Pvt. Ltd	In light of earlier recommendations dated 24.02.2025, the firm has presented data on safety and efficacy, field trial, justification for no. of animals for study, specific indications for pre mating, mating and pregnant and lactating dogs, Post Marketing Surveillance, hepatotoxicity, renal toxicity data before the committee and the committee accepted the justification and data submitted by the firm. After detailed deliberation, the committee recommended for grant of Import and Marketing of Afoxolaner 11.3 mg/28.3/68/136 mg chewable tablets for treatment of Dogs for proposed indications.
2.	F.No.Vet-11011(16)/17/2024-12581 Afoxolaner and milbemyacin oxime chewable tablets: 9.375 mg/1.875mg, 18.75 mg/3.75 mg, 37.5 mg/7.5 mg, 75 mg/15 mg, 150 mg/30 mg. For treatment of Dogs	M/s Boehringer-Ingelheim India Pvt. Ltd	In light of earlier recommendations dated 24.02.2025, the firm has presented data on safety and efficacy, information on field trial data, Post Marketing Surveillance, hepatotoxicity, renal toxicity data before the committee and the committee accepted the justifications and data submitted by the firm. After detailed deliberation, the committee recommended for grant of Import and Marketing of Afoxolaner and milbemyacin oxime chewable tablets: 9.375 mg/1.875 mg, 18.75 mg/3.75 mg, 37.5 mg/7.5 mg, 75 mg/15 mg, and 150 mg/30 mg for treatment of Dogs for proposed indications.
3.	F.No.Vet-11011(11)/31/2024-10422 Esafoxolaner (1.2%W/v), Eprinomectin (0.4%W/v), Praziquantel (8.3%w/v) Spot on solution. For treatment of Cats	M/s Boehringer-Ingelheim India Pvt. Ltd	In light of earlier recommendations dated 24.02.2025, the firm has presented data on rationality of proposed FDC, potential accumulation of FDC including hepatotoxicity and renal toxicity data, justification with respect to no. of animals, onset and duration of pupil dilation and time for reversal of the same and submission of multiple dose toxicity data, prescribing information before the committee and the committee accepted the justification and data submitted by the firm.

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			After detailed deliberation, the committee recommended for grant of Import and Marketing of Esafoxolaner (1.2%W/v), Eprinomectin (0.4 % W/v), Praziquantel (8.3 % w/v) Spot on solution for treatment of Cats for proposed indications.
4.	F.No.Vet-11011(11)/21/2024-7599 Oclacitinib Maleate Chewable Tablet 5.4 mg and Oclacitinib Maleate Chewable Tablet 16 mg. For treatment of Dogs	M/s Zoetis India Ltd	In light of earlier recommendations dated 24.02.2025, the firm presented justification including BE study data before the committee and the committee accepted the justification and data presented by the firm. After detailed deliberation, the committee recommended for grant of Import and Marketing of Oclacitinib Maleate Chewable Tablet 5.4 mg and Oclacitinib Maleate Chewable Tablet 16 mg for treatment of Dogs for indications as approved for Oclacitinib Maleate film coated tablets 5.4 mg and 16 mg.
5.	F.No VET-11011(11)/33/2024-10731 Deslorelin Acetate 4.7mg subcutaneous implant for female Dogs & Male Cats. For treatment of Female Dogs & Male Cats	M/s Virbac Animal Health	In light of earlier recommendations dated 24.02.2025, the firm presented justification for clear indication, contraindication, duration and withdrawal complications, Target Animal Safety Study, withdrawal effects of the products on reversibility of reproductive organs and reproductive behavioral effects and productivity before the committee and the committee accepted the justification and data submitted by the firm. After detailed deliberation, the committee recommended for grant of Import and Marketing of Deslorelin Acetate 4.7 mg subcutaneous implant for female Dogs & Male Cats for treatment of female Dogs & Male Cats for proposed indications.
6.	F.No.VET-11011(11)/6/2025-19831 Trilostane (Vetoryl hard capsules 10, 30 & 60 mg) For treatment of Dogs	M/s Panav Bio-tech	The firm did not turn up for the presentation.
7.	F.No.: - VET-11011(11)/70/2024-17945	M/s Huvepharma Sea (Pune) Pvt. ltd	The proposal of the firm for import and marketing of Tilmicosin Phosphate USP (Tilmovet 20%) Premix for medicated

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	<p>Tilmicosin Phosphate USP (Tilmovet 20%) Premix for medicated feeding stuff. For treatment of Pigs & Chickens</p>		<p>feeding stuff for treatment of Pigs & Chickens.</p> <p>After detailed deliberation, the committee recommended the firm to submit clarifications/justification on the following.</p> <ul style="list-style-type: none"> • Data on residual limits of the Tilmicosin Phosphate USP Tilmovet 20%) in chickens (Layers and Broilers). • Minimum Inhibitory concentration of the Tilmicosin Phosphate USP Tilmovet 20%) in chickens (Layers and Broilers) is same for Mycoplasma gallisepticum and Mycoplasma synoviae. • Cardiovascular issues in pigs associated with IV administration of Tilmicosin Phosphate USP (Tilmovet 20%) – Expert opinion from ICAR–National Research Centre for Pigs (ICAR-NRCP), Guwahati, on the assessment of the impact on the cardiovascular system following any accidental (e.g., oral injury) entry of the drug to the bloodstream. • Toxicity data of Tilmicosin Phosphate USP Tilmovet 20%) in pigs and chickens. • Firm shall submit proposed risk-management plan for monitoring resistance development post-marketing.
8.	<p>F. No. VET-11011(11)/17/2025-23351</p> <p>Maropitant Citrate Injectable Solution 10 mg/ml. For treatment of Dogs & cats</p>	M/s Zoetis India Ltd	<p>The proposal of the firm for import and marketing of Maropitant Citrate Injectable Solution 10mg/ml for treatment of Dogs & cats for wavier of bridging study/field trials was deliberated in the meeting. The firm presented field trial data on safety and efficacy conducted in USA.</p> <p>After detailed deliberation, the committee recommended for wavier local field trials/bridging trials for the grant of Import and Marketing of Maropitant Citrate Injectable Solution 10mg/ml for treatment of Dogs & cats for proposed</p>

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			indications.
9.	<p>F. No. Vet/Form44/FF/2025/48540</p> <p>Fluralaner 150 mg/ml powder and solvent for suspension for injection for dogs (Bravecto). For treatment of Dogs</p>	M/s Intervet India Pvt.Ltd	<p>The proposal of the firm for import and marketing of Fluralaner 150mg/ml powder and solvent for suspension for injection for dogs (Bravecto) for treatment of Dogs was deliberated in the meeting. The firm presented trial data of field studies conducted in Europe and Australia.</p> <p>The committee notes that the formulations Fluralaner 10 mg/ml Exzolt Solution and Fluralaner chewable Tablet 112.5/250/500/1000/1400 mg is approved for other indications.</p> <p>After detailed deliberation, the committee recommended for grant of Import and Marketing of Fluralaner 150mg/ml powder and solvent for suspension for injection for dogs (Bravecto) for treatment of Dogs for proposed indications.</p>