Recommendations of the SEC (Veterinary) made in its 01st/26 meeting held on 19.05.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Veterinary Division			
1.	F.No: VET/Form44/FF/2025/ 51500 Toceranib Phosphate Film coated Tablets 10 mg, 15 mg and 50 mg for dogs (Brand Name: Palladia) (New Drug-Import Permission)	M/s Zoetis India Limited	The firm presented the summary of the following study: "Multi center, placebo controlled, double blind, randomized study of oral Toceranib Phosphate Film Coated Tablets in the treatment of Dogs with recurrent mast cell tumors (effectiveness analysis& safety analysis in dogs for the duration of six weeks". The committee noted the following. 1. Toceranib Phosphate film coated tablets 10 mg,15 mg and 50 mg have been approved by EU, USA, Canada & New Zealand under the brand name "Palladia" for the treatment of non-resectable Patnaik grade II (intermediate grade) or III (high grade), recurrent, cutaneous mast cell tumours in dogs. 2. The product has been marketed since 2009. In view of above, and after detailed deliberation, the committee recommended that the firm should submit the below mentioned data for further deliberation. a) Firm should submit the study data on drug interaction with other routinely prescribed co-administered drug product for treatment of dogs in India. b) Justification for the proposed dosage regimen claimed as 3.25 mg/kg body weight in dogs with supportive evidences. In view of the above and after detailed deliberation the Committee recommended that the firm should submit the above mentioned data for further deliberation.
2.	F.No: VET/Form44/FF/2025/ 51899	M/s Zoetis India Limited	The firm presented the summary of the following studies: 1) Negative control, randomized clinical

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Bismuth sub nitrate intramammary suspension-2.6 g per 4 g syringe (65.000 % w/w) for cows (Brand Name: Orbeseal) (New Drug-Import Permission)		field effectiveness study to determine the incidence of new intramammary infections during the dry period following intramammary infusion of Teat Seal (Orbeseal) (Bismuth sub nitrate intramammary suspension, prefilled syringe) in dairy cows approaching the end of lactation for the duration of 60 days. 2) Positive control, randomized, blinded clinical field effectiveness study to determine the incidence of new intramammary infections during the dry period following intramammary infusion of teat seal (Bismuth sub nitrate intramammary suspension, prefilled syringe) in Dairy Cows approaching the end of lactation for the duration of 60 days". The committee noted the following. Bismuth subnitrate intramammary suspension pre-filled syringe 65.000%w/w (Brand Name: Orbeseal) has been approved by EU, UK, Australia, Japan & Canada & Ireland under the Brand Name "Orbeseal" for prevention of new intramammary infections of dairy cattle (cow) throughout the dry period. In view of above, and after detailed deliberation, the committee recommended the following for further deliberation: a) Firm should submit study data of the proposed product in Indian dairy cowbreeds with emphasis on efficacy (somatic cell counts and clinical mastitis scoring), and safety endpoints (Residual drug in raw milk). b) Validate the appropriate stripping method postpartum with Specific reference to Indian Dairy Cow breeds.
3.	F.No:- VET/Form44/FF/2025/ 52496 Ilunocitinib 4.8 mg, 6.4 mg, 8.5 mg, 15 mg film- coated tablets for dogs	M/s Elanco India Pvt Ltd	The firm presented the summary of the following studies: 1. ELA1700407: 6-Month Pilot Study of LY3411067 by Oral Gavage in 9-Month-Old Beagle Dogs Lourens, 2020 in beagle dogs. 2. ELA1900084: A 6 Month Oral (Tablet)

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	(Brand Name: Zenrelia) (New Drug-Import Permission)		Safety Study of LY3411067 in 12 Month Old Beagle Dogs. 3. ELA210188: LY3411067: A 6-Month Oral (Tablet) Safety Study in 11- to 12-Month Old Beagle Dogs. 4. ELAVV200035: The Effect of Oral LY3411067 on the Response to Primary Vaccination in Dogs. 5. NAH-15-185: Efficacy of JAK-inhibitor, LSN3103802 and LSN3103803, to Control Skin Lesions and Pruritus Induced by Challenge in a Canine Model of HDM Sensitised Dogs. 6. 16-EL-001: Dose Determination Study for Janus Kinase Inhibitors LSN3103802 and LSN3103803 in dogs. 7. ELA1600455: Duration of Efficacy for Janus Kinase Inhibitors LSN3103802 and LSN3103803 in dogs. 8. ELA1700243: Efficacy of LY3411066 at 0.4 mg/kg and LY3411067 at 0.4 and 1.2 mg/kg q24h to Control Skin Lesions and Pruritus Induced in House Dust Mites – Sensitized Dogs. 9. ELA1700239: Efficacy of LY3411067 to Control Skin Lesions and Pruritus Induced in House Dust Mite Sensitized Dogs. 10. ELA1800280: Efficacy and Field Safety of Once Daily Oral Administration of LY3411067 for Control of Pruritus and Skin Lesions Associated with Allergic Dermatitis in Client-Owned Dogs. The committee noted the following: Ilunocitinib 4.8 mg, 6.4 mg, 8.5 mg, 15 mg film-coated tablets for dogs (Brand name: Zenrelia) has approved by USA, for 1) Treatment of pruritus associated with allergic dermatitis in dogs. 2) Treatment of clinical manifestations of atopic dermatitis in dogs. In view of above, and after detailed deliberation, the committee recommended that the firm should submit the scientific justification and supporting data on the recommended withdrawal period associated with the vaccines under routine veterinary practices (in client-owned dogs),

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			for further deliberation.
4.	F.No. VET/Form44/FF/2026/ 55844 Docetaxel Lipid Suspension for Injection 20 mg/vial for dogs (Brand name: Doce Aqualip-Pet) (New Drug-Domestic Manufacturing)	M/s Intas Pharmaceuticals Ltd.	The firm presented the summary of study no. V/15/069 titled as "Comparative Efficacy of Zinc Oxide Nanoparticle Conjugated Docetaxel and Docetaxel Alone for Mammary Tumour in Dogs" conducted in academic setup. The committee noted the following. 1. Docetaxel Lipid Suspension for Injection 20 mg/vial was approved for the treatment of human patients with different types of carcinoma. 2. Firm has applied for the following indications for veterinary use in dogs: • Non-resectable stage III, IV or V mammary carcinoma in dogs that have not received previous chemotherapy or radiotherapy. • Along with or after surgery in mammary carcinomas to avoid chances of recurrence. In view of above, and after detailed deliberation, the committee recommended that the firm should submit a formal study protocol for conduct of the field trial of the applied drug product (Docetaxel Lipid Suspension for Injection 20 mg/vial) in Indian dog population including appropriate dose selection, safety and efficacy analysis endpoints for further deliberation.
5.	F.No: VET/Form44/FF/2025 /52767 Doramectin= 5.000 mg/ml and Levamisole=150.0000 mg/ml Solution for injection for cows (Brand Name: Valcor) (New Drug-Import Permission (FDC))	M/s Zoetis India Limited	The firm presented the summary of the following studies: 1. Efficacy of a Doramectin Levamisole fixed-dose combination injectable formula against field nematode infections in cattle (cow mixed breed). 2. Assessment of therapeutic and persistent efficacy of an injectable fixed dose combination of Doramectin and Levamisole hydrochloride against an artificially induced infestation of Rhipicephalus microplus in cattle. 3. Therapeutic efficacy of a Doramectin Levamisole fixed-dose combination injectable formulation administered subcutaneously to cattle naturally

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			infested with sucking lice in dairy and beef breed cattle for the period of 56 days". The committee noted the following. 1. Doramectin 5.000 mg/ml and Levamisole 150.0000 mg/ml Solution for injection has been approved by USA, under the Brand Name "Valcor" for the treatment and control of gastrointestinal roundworms (adults and fourth stage larvae) - Ostertagia ostertagi (including inhibited larvae), O. lyrata, Haemonchus placei, Trichostrongylus axei, T. colubriformis, T. longispicularis*, Cooperia oncophora, C. pectinata*, C. punctata, C. surnabada, Bunostomum phlebotomum*, Strongyloides papillosus*, Oesophagostomum radiatum, Trichuris spp.*, and Nematodirus helvetianus*; lungworms (adults and fourth stage larvae)- Dictyocaulus viviparus; eye worms (adults) - Thelazia spp.; grubs (parasitic stages) - Hypoderma bovis and H. lineatum; sucking lice – Haematopinus eurysternus, Linognathus vituli, and Solenopotes capillatus; mange mites - Psoroptes bovis and Sarcoptes scabiei.(* adults) In view of above and after detailed deliberation, the committee recommended the following for further deliberation. The firm should submit: a) The drug interaction or contraindication study data with the applied drug product. b) Justification for the proposed FDC dosage vs. individual dose administration of the Doramectin & Levamisole with emphasis onprevalence data on anti-parasitic resistance in India. c) Maximum residual limit data of each of drug (Doramectin & Levamisole) that is approved for use in the veterinary population (dairy cows) in India.
6.	F.No: VET-11011(16)/1/2025-18746	M/s Zoetis India Ltd	The firm presented the summary of the following studies:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Sarolaner = 6 mg, 12 mg, 24 mg, 48 mg, 72 mg / Moxidectin= 0.12 mg, 0.24 mg, 0.48 mg,0.96 mg, 1.44 mg / Pyrantel embonate= 25 mg, 50 mg, 100 mg, 200 mg, 300 mg Chewable Tablets for dogs		1. Efficacy and Safety of Simparica Trio (Sarolaner/Moxidectin /Pyrantel) in the treatment of Natural Infestations of Sarcoptes scabiei on Dogs for the period of two months. 2. Efficacy and Safety of Simparica Trio in the Treatment of Natural Infestations of Demodex spp. on Dogs for the duration of three months. 3. Evaluation of the preventive efficacy of a monthly treatment regimen with Simparica Trio against canine eye worm infection (caused by Thelazia callipaeda) in dogs for the period of 150 days. 4. To confirm the efficacy of a single oral administration of a combination of Simparica trio chewable tablet in the prevention of induced Angiostrongylus vasorum (A. vasorum) infections in dogs in dogs for the period of 64/66 days" The committee noted the following. 1) The product [Sarolaner/Moxidectin /Pyrantel embonate Chewable Tablets (Sarolaner: 6 mg/12 mg/24 mg/48 mg/72 mg, Moxidectin: 0.12 mg/0.24 mg/0.48 mg/0.96 mg/1.44 mg, Pyrantelembonate: 25 mg/50 mg/10 mg/200 mg/300 mg)] is already approved and marketed in India in the following indications: a. Ectoparasite: Treatment of tick infestation. Treatment of flea infestations (*Ctenocephalides felis* and *Ctenocephalides canis*). As part of a treatment strategy for the control of flea allergy dermatitis (FAD). b. Gastrointestinal Nematodes: for the treatment and control of gastrointestinal roundworm and hookworm infections *Toxocara canis* immature adults (L5) and adults .*Ancylostoma caninum* L4 Larvae, immature adults (L5) and adults. *Toxascaris leonine* adults *Uncinaria stenocephala* adults. c. Vascular Nematodes: for the prevention of heartworm disease (*Dirofilaria immitis*).

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			2) The product has already approved for proposed additional indications in various countries including EMA. 3) As per the safety summary presented by the Firm, there are no additional safety concerns. 4) Now the firm has applied for following additional indications: a. For the treatment of sarcoptic mange (caused by Sarcoptes scabiei var. canis). b. For the treatment of demodicosis (caused by Demodex canis) c. For the prevention of establishment of thelaziosis (adult Thelazia callipaeda eye worm infection) d. For the prevention of angiostrongylosis by reducing the level of infection with immature adult (L5) stages of Angiostrongylus vasorum. In view of the above and after detailed deliberation, the committee recommended for the grant of permission for the proposed additional indication subject to condition that the firm should submit: a. the safety data for the approved indication in Indian dog population, b. the proposal for conduct of active post marketing safety surveillance study within three months from the approval of the product.
7.	F.No:- VET/Form44/FF/2025/ 50688 Hydrocortisone Aceponate 0.584 mg/ml (Cutaneous spray solution) for dogs	M/s Virbac Animal Health India Pvt. Ltd	The firm presented the summary of following study, “Efficacy of a 0.0584% Hydrocortisone Aceponate Spray in the management of canine atopic dermatitis: a randomized, double blind, placebo-controlled trial in dogs”. The committee noted the following. 1. Drug-Hydrocortisone Aceponate 0.584 mg/ml cutaneous spray solution is already approved for the indication “symptomatic treatment of inflammatory and Pruritic dermatosis in dogs”. 2. The product is already approved for proposed additional indications in various countries including EMA.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			3. As per the safety summary presented by the Firm, there is no additional safety concern. 4. Now the firm has applied for an additional indications "For alleviation of clinical signs associated with atopic dermatitis in dogs" In view of the above and after detailed deliberation, the committee recommended for the grant of permission for the proposed additional indication subject to following condition that the Firm should submit: a. the safety data for the approved indication in Indian dog population. b. the proposal for conduct of active post marketing safety surveillance study within three months from the approval of the product.