

VETERINARY PHARMACOVIGILANCE SURVEY CONDUCTED IN TAMIL NADU STATE, INDIA – A STATUS REPORT

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ABSTRACT

In India there is no present government policy to survey and evaluate adverse drug events (ADEs) / Pharmacovigilance programme in veterinary medicine. Therefore, essential information such as frequency, severity of treated animal ADRs and reliable data about frequent ADR-producing drugs remains unknown. The objective of the study is to assess and communicate risks and benefits in the market. Ultimately to educate the veterinarians and the stake holders on the safety and efficacy of veterinary drugs and biologicals.

To this purpose, a 12 month pilot study based on WHO recommendations was conducted to monitor ADRs in the livestock treated by field veterinarian in the state of Tamil Nadu in India for frequently used drugs and common labeled signs.

The present study warrants for the need for sustained veterinary pharmacovigilance programmers in livestock for timely ADR presenting drug reactions and drug safety improvement.

Keywords: Veterinary Pharmacovigilance, ADRs, efficacy, livestock

INTRODUCTION

A Pharmacovigilance survey on usage of veterinary medicinal products in Tamil Nadu state was conducted for the period from January 2011- March 2012. A format has been designed including the data on commonly used drugs in veterinary treatment, Extra Label usage of drugs in food animals and voluntary reporting system on Adverse Drug Reactions (ADRs).

One hundred and seventy two (172) field veterinarians were voluntarily participated, representing various districts of Tamil Nadu (Ariyalur -1, Chennai-17, Coimbatore-2, Cuddalore-3, Dharmapuri-7, Dindigul-5, Kancheepuram-11, Karur-2, Krishnagiri-3, Madurai-4, Namakkal-1, Perambalur-1, Pudukottai-6, Ramanathapuram-5, Salem-4, Sivaganga-7, Thanjavur-1, Theni-5, Thirunelveli-2, Thiruvallur-14, Thiruvannamalai-13, Tiruppur-9, Tuticorin-11, Vellore-7, Villupuram-29, Virudhunagar-2).

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I. Adverse Drug Reactions Reported

Class of drug	Drugs	Species	ADR Reported	No of ADR Reported
Antibiotics/ Antimicrobials	Oxytetracycline	Cattle	i.m, preparation - but given through i.v route, 90ml along with DS, after 30 minutes animal collapsed	1
	Oxytetracycline	Cattle	Pain, swelling, staggering gait, giddiness, sudden fell down, urination, respiratory distress -asphyxia	9
	Oxytetracycline	Goat	Pain, swelling, giddiness, Nervous symptoms	2
	Tetracycline	Cattle	Edema at injection site	1
	Strepto-penicillin	Cattle	Salivation, Anaphylaxis, exaggerated allergic skin reactions, giddiness, allergic swelling over the body, death	7
	Streptomycin	Cattle	Death	1
	Enrofloxacin	Dog	Giddiness	1
		Cattle	Allergic reactions, salivation, mydriasis	2
		Calf	Collapsed after i.v injection	1
	Ciprofloxacin	Cattle	Shivering, tremor, abdominal coughing	1
	Chloramphenicol	Goat	Abortion	1

Veterinary Pharmacovigilance survey conducted

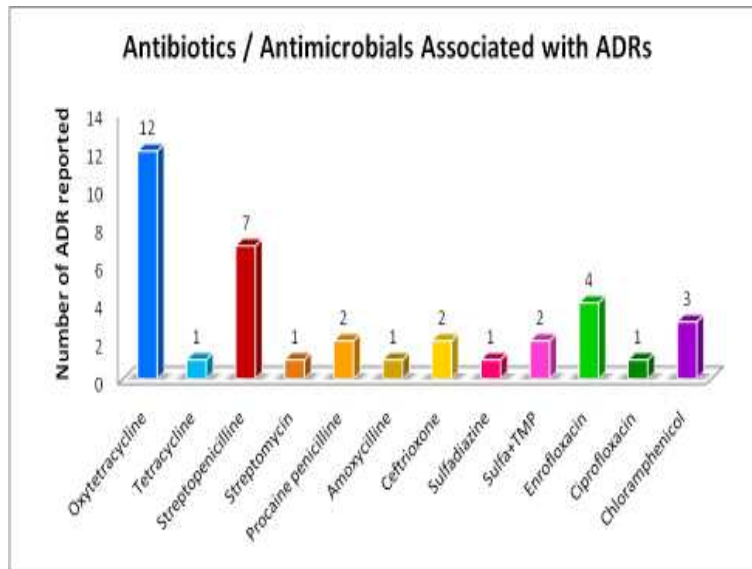
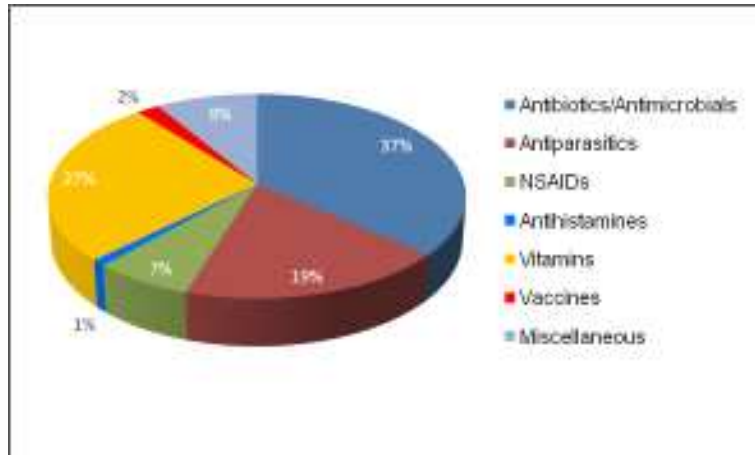
		Cattle	Urticaria, tremor	2
	Procaine penicillin	Cattle	Death	1
	Penicillin	Goat	Allergic reactions	1
	Amoxycillin	Cattle	Hyperactivity, Allergic reaction	1
	Ceftriaxone	Cattle	Anaphylactic reaction, ocular edema, Skin rashes	2
	Sulfadiazine	Cattle	Skin eruptions	1
	Sulfa+trimetho prime	Cattle	Bradycardia, Suddenly fell down, Urticari, Salivation, Kicking of legs	2
Antiparasitics	Levamisole	Dog	Salivation, Nervous signs, Tremor, Death	1
		Goat	Nervous symptoms, Sudden fall down, Death	2
		Cattle	Tremor, enteritis	1
	Butox (Deltamethrin)	Dog	Extensive salivation	1
		Goat	Off feed	1
	Tetramisole	Sheep & Goat	Excessive salivation, Anorexia, shivering, extended head, collapsed	4
	Tetramisole	Cattle	Salivation, nervous symptoms, staggering gait, shock	4
	Ivermectin	Dog	Tremor, severe convulsion	1
	Berenil	Cattle	Colic, frequent falling down, shivering, Cyanosis of mucous membranes, Salivation, Allergic reactions	4

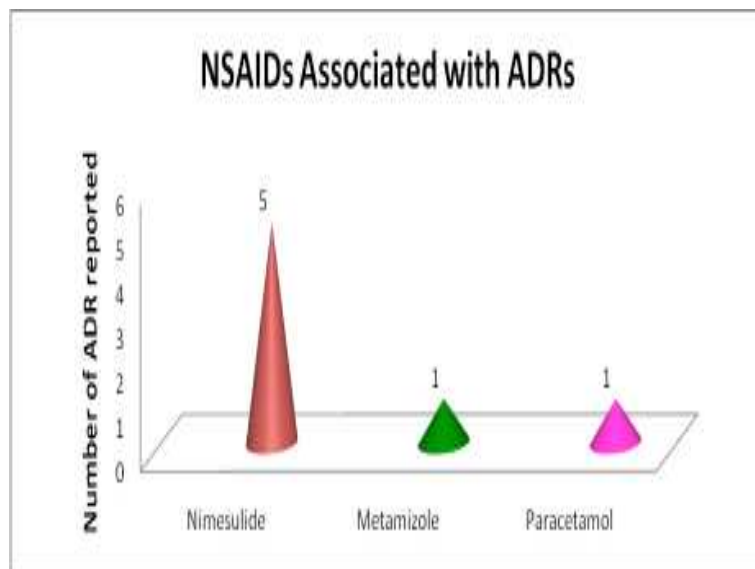
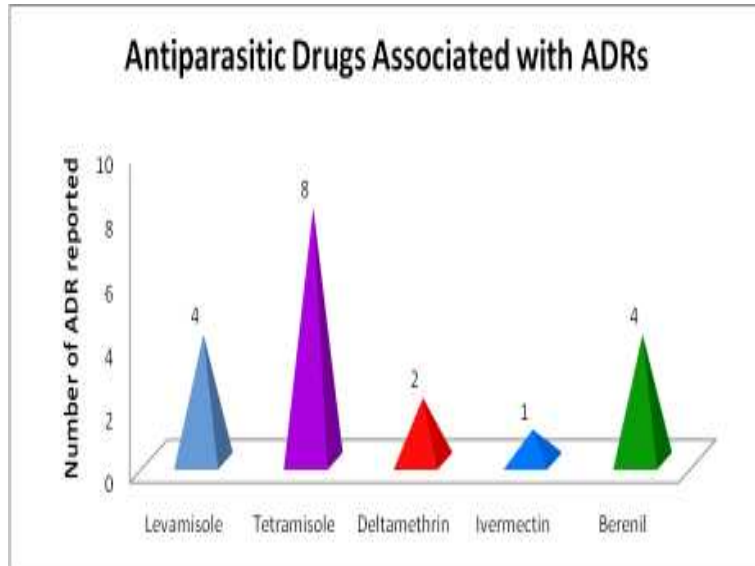
NSAIDS	Nimesulide	Cattle	Muscular Tremor, Abortion	3
		Sheep & Goat	Paraplegia	1
		Dog	Severe pain	1
	Analgin (Metamizole)	Cattle	Tremor	1
	Paracetamol	Cattle	Nervous symptoms	1
Antihistamines	Ranitidine	Dog	Convulsion	1
Vitamins	Vitamin-E and Selenium	Dog	Allergic reactions	2
		Cattle, Sheep & Goat	Salivation, Shivering, Cutaneous eruptions, Allergic reactions, Shock, Death	5
	Multivitamins	Dog	Allergic reaction, skin erythema, shivering	2
		Cattle	Shock and death	2
		Cattle	Anorectic, Salivation, Allergic reactions, sudden fell down	5
		Heifer	Jerking of limbs	1
	Vitamin – A	Cattle	Anaphylactic reaction	1
		Dog	Facial edema, Salivation, Reddening of skin, itching sensation	2
	B-complex	Dog	Salivation, Vomiting, Allergic reaction, swelling of eyes, Unconsciousness	2
		Goat	Respiratory distress	1

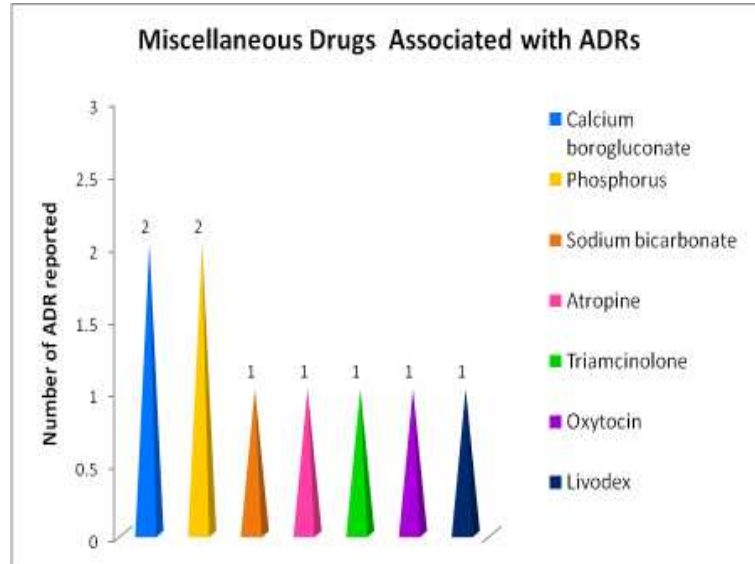
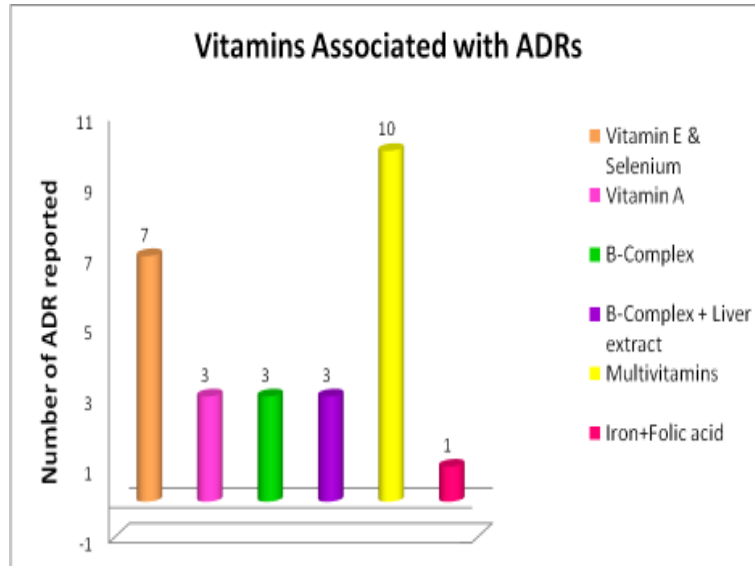
Veterinary Pharmacovigilance survey conducted

	B-complex with liver extract	Cattle	Anaphylactic reaction, hyperesthesia, convulsion	2
		goat	Nervous signs	1
	Feritas (Iron, sorbitol, citric acid, Folic acid, Hydroxocobal amine acetate)	Cattle	Swelling of head, salivation, tremors, death	1
Vaccines	FMD	Cattle, goat	Hoof lesions developed, Animal fell down	2
Miscellaneous Drugs	Calcium borogluconate	Cattle	Tremor, fell down but recovered after few minutes	2
	Phosphorus (ND -PHOS)	Cattle, Goat,	Local swelling and Inflammatory changes, Dyspnoea	2
	Sodium bicarbonate	Goat	Pain, pedalling movement	1
	Atropine	Elephants	Tremor, severe mydriasis	1
	Triamcinolone	Cattle	Salivation, erythema, eruptions, respiratory distress	1
	Oxytocin	Cattle	Death	1
	Livodex	Cattle	Nervous symptoms	1
	TOTAL NUMBER of ADRs REPORTED			

Drugs Associated with ADRs
Sources of ADEs recorded from 2011-2012 in Tamil Nadu State, India







II. Extra-label Usage of Drugs

Class	Drugs	Route of Administration
Antimicrobials/ Antibiotics	Chloramphenicol	Parenteral
	Ceftriaxone, Cefotaxime	Parenteral
	Amoxicillin, Ampicillin, Clavulanic acid	Oral
	Dicloxacillin	Parenteral
	Gentamicin, Amikacin, Kanamycin	Parenteral
	Ciprofloxacin, Ofloxacin,	Oral, Parenteral
	Gatifloxacin	Topical
	Metronidazole	Parenteral
	Oxytetracycline	Intra uterine route
	Doxycycline	Oral
Antiparasitic	Fenbendazole	Oral
	Pyrantal pamoate	Oral
	Metronidazole + Ciprofloxacin	Oral
Class	Drugs	Route of Administration
Antimastitis drugs	Colistin	Intra-mammary
	Chloramphenicol	Intra-mammary

Antihistamines	Ranitidine	Parenteral
Antiulcer	Omeprazole, Pantaprazole	Oral
	Digene gel	Oral
NSAIDs	Paracetamol	Oral, Parenteral
	Chlorpheniramine maleate	Oral, Parenteral
	Diclofenac	Oral, Parenteral
	Nimesulide	Oral, Parenteral
Class	Drugs	Route of Administration
Antiemetics	Domperidone	Oral, Parenteral
	Metaclopramide	Oral, Parenteral
	Phenothiazine	Oral
	Ondansetrone	Parenteral, oral
Antifungals	Miconazole	Topical
	Ketaconazole	Topical
Diuretics	Lasix (Furosemide)	Parenteral
Antineoplastics	Vincristin	Parenteral
Vitamins	Zincovit	Oral
	Neurobion	Parenteral
	Vitamin-C	Oral

Class	Drugs	Route of Administration
Miscellaneous	Dicyclomine	Oral
	Neosporin powder	Oral
	Loparamide	Oral
	Thiopentone	Parenteral
	Oxytocin	Parenteral
	DNS, RL	Parenteral
	Insulin	Parenteral
	Bromocriptine	Oral
	Dexamethasone	Parenteral
	Prednisolone	Oral
	Cremaffin	Oral
	Tetanus Toxoid	Parenteral
	Placentrex	Parenteral
	Dexorange	Oral
	Cyproheptadine syrup/tablet	Oral
	ORS electrolytes	Oral
Homeopathy preparations	Phytolaceaberry pills, Tuja pills	Oral

	ADRs	Extra Label Usage of Drugs
Ariyalur (1)	Levamisole in dog, salivation nervous signs, tremor, death	-
Chennai (17)	Butox, dog, extensive salivation & in goat, off feed. FMD vaccine, goat & cattle, hoof lesions developed	Nemocid (Pyrantel pamoate) Nice tablets, zincovit Neopsorin powder Amoxycillin (2), Ampicillin (3), Cephalosporin (2), Metronidazole, Chloramphenicol Paracetamol Overan, Oxytocin (2) Bromocriptine, metaclopramide
Coimbatore (2)	Vitamin preparation, dog, allergic reaction, skin erythema Streptomycin, Cattle, animal died	Cefotaxime, Ceftriaxone Metranidazole+Ciprofloxacin Ondansetron Paracetamol
Cuddalore (3)	-	Taxim, gentamicin Rantac, domstal Epidrin Neurobion, paracetamol
Dharmapuri (7)	Streptopenicillin Anaphylaxis in cattle Vit A inj in cattle Anaphylactic reaction Nimesulide muscular tremors in cattle Ferritas in cattle, Swelling of head, salivation, tremors, death OTC LA, goat, nervous symptoms Tetramisole powder, sheep & goat, Excessive salivation Multivitamin inj, cattle, shock & death Mifox/calboral inj, cattle, sudden death Hivit inj, cattle, sudden collapse Berenil inj severe colic in cattle	Metaclopramide (3), Chloramphenicol, OxytocinDicyclomine, AnalginDexamethasone, Imferon Butalux Lasix, Frusemide Ranitidine DNS, RL

Dindigul (5)	Streptopenicilline, cattle, Anaphylaxis Berenil inj in cattle generalised allergic reaction	Ranitidine in dogs (2) Metaclopramide, Placentrix Paracetamol, Diclofenac Neurobion forte, Frusemide
Kancheepuram (11)	Calcium boro gluconate / carboral, cattle, tremor, fell down but after few minutes recovered OTC, i.m, preparation - but given th' i.v 90ml along with DS, after 30 minutes animal collapsed Enrofloxacin, dog, giddiness Streptopenicillin, Anaphylaxis	Clavulanate, Cephalexin (3), Dicloxacillin, Kanamycin, Ampicillin Domperidone, Metaclopramide (4) Ketaconazole (Topical), Gatifloxacin (topical) Piroxicam, Aspirin, Nimesulide, Diclofenan Omeprazole, Ranitidine (3) Trifluprednisone, neurobion forte(2) Benzyl peroxide Pyrantel pamoate, Betnesol, Nice
Karur (2)	-	Diclofenac Metaclopramide Metronidazole & terramycin liquid as topical Application
Krishnagiri (3)	Tribivet, dog, Allergic reaction, swelling of eyes Tetramisole, cattle, salivation, nervous symptoms, staggering gait OTC, cattle, staggering gait	Perinorm Dicyclomine for colic in cows Cremaffin for constipation in calf Tetanus toxoid inj for S&G (2) Ranitidine, inj & tab., Neurobion inj & tab
Madurai (4)	E care Se, goat & cattle, allergic reaction, death (2) E care Se, dog, allergic reaction Hivit-multivitamin, cattle, Shivering, Allergic reactions Entrostrong 20%, cow, Allergic reactions	Amikacin, Cephataxin, Fentaplozole Perinorm (2), Normet Polybion, Dexorange Cyclopam, Phexin

	B-complex with liver extract, cow, allergic reaction	Drez ointment, Calmpose
Namakkal (1)	Livobex, cattle, Allergic reactions	-
Perambalur (1)	Enrofloxacin, cattle, salivation, mydriasis OTC, cattle, suddenly fell down, urination	Diclofenac Dexamethasone Digene gel
Pudukottai (6)	-	Metaclopramide (2) Neurobion Vitamin drops in dogs
Ramanathapuram (5)	Vit E Se inj, cattle, Salivation, shivering, cutaneous eruptions & Shock (2) Phosphorus (ND-PHOS), Cattle, goat, local swelling and Inflammatory changes B-Complex, Dog, Salivation, vomiting, Unconsciousness Ciprofloxacin, cattle, Shivering, tremor, abdominal coughing	Ceftriaxone, Streptochrome (styptic) Ondansetron, perinorm Paracetamol & Mefenamic acid Placentrix (2)
Salem (4)	-	Ondansetron Metaclopramide
Sivaganga (7)	Vitamin A, dog, Facial edema, salivation Vitamin B complex with choline, cattle, hyperaesthesia, convulsions Vitamin B complex with liver extract with choline, goat, nervous signs Chloramphenicol, goat, abortion Chloramphenicol, cattle, urticaria Nimesulide, S&G, paraplegia Tetramisole, cattle, Salivation, shock Amoxycillin, Cattle, Hyperactivity, Allergic reaction	Ofloxacin (2), Taxim Zole-F (2) Avomin, Perinorm Digene gel (3), Dicyclomine, Ranitidine (3), Pantocid Diclofenac Gentamycin&Dexamethasone combination eye drops Liv-52, Neurobion (2), Dexorange, Rerve plus Lasix, Valium, Podowart, Placentrex

Theni (5)	<p>Tetramisole, sheep, shivering, extended head, collapsed Chlorpheniramine maleate,</p> <p>Streptopenicillin, cattle, allergy</p>	<p>Diclofenac (2),</p> <p>Piraxicam Dexamethasone Metaclopramide Neurobion</p>
Thirunelveli (2)	-	<p>Gentamicin Chlorphenairamine maleate Prednisolone</p>
Thiruvallur (14)	<p>Levamisole, goat, nervous symptoms</p> <p>Tetramisole, calf, nervous symptoms</p> <p>OTC, cattle, sudden fall down Nimesulide, dog, severe pain symptoms</p> <p>Nilworm, sheep, adverse reactions noticed Tetracycline, i.m inj, cattle, edema at injection site Calcium mag, cattle, sudden fall of animal Penicillin, goat, allergic reaction Chloramphenicol, cattle, tremor</p> <p>Ivermectin, dog, tremor, severe convulsion Atropine in elephants, tremor, severe mydriasis, mania</p>	<p>Toxim-O, Amoxicillin clavulanate Cepoderm, Garamycin, Amikacin, Gentamicin (in i/mammary route) Haemoceal Estar-200, Nutriccoat powder Vomikind inj, Perinorm (3), Ranitidine (2) Eldevit, Vit-C Nemocid OTC in I/U route Streptopenicillin i/uterine as post insemination Antibiotic</p>
Thiruvannamalai (13)	<p>Ceftriaxone Anaphylactic reaction in cattle</p> <p>Hivit - jerking of limbs in heifer</p> <p>Streptopenicillin, cattle, salivation, exaggerated allergic skin reactions</p> <p>Enrofloxacin, calf, immediately after IV inj animal collapsed Tetramizole, goat, collapse of animal within half an hour OTC, cattle, restlessness, fell down for 10 minutes Analgin, cattle, tremors</p>	<p>Diclofenac (4), paracetamol (2)</p> <p>Ranitidine(2), metaclopramide(2) Gentamicin in large animal, Ampicillin & cloxacillin Ofloxacin+Dexa eye drops, Injectable OTC in I/uterine therapy Pantaprazole B-Plex, Neurobion forte, Vit-K Oxytocin, Estrogen, Pyrantel pamoate</p>

Tiruppur (9)	<p>Hivit in cattle allergic reaction, sudden fall (2) Ranitidine, IV inj dog, convulsion FMD Vaccine, cattle, animal fell down Berenil, cattle, pain, frequent falling down & shivering Tetramisole, S&G, excessive salivation, anorexia Sulpha+Trimethoprim, cattle, bradycardia, fell down Streptopenicillin, cattle, salivation, giddiness, allergic swelling over the body, death (2) OTC, I.V., Cattle, giddiness, fell down and becomes normal (2)</p>	<p>Antivenin Stryptovit-K Dicyclomine Metaclopramide Neostigmine Neurobion forte</p>
Tuticorin (11)	<p>Sodabicarb, goat, pain, pedaling movement</p> <p>Ceftriaxone, cattle, ocular edema, peteches in the skin Bactrisol, cattle, Urticaria, salivation, kicking of leg Berenil, cattle, salivation, cyanosis of mucous membrane (2) B-Complex inj, goat, respiratory distress</p> <p>Vit A inj, dog, reddening of the skin, itching sensation</p> <p>E care se, death in Goat & allergic reactions in cattle Nimesulide, cattle, abortion</p>	<p>Ciprobid tablet, gentamycin eye drops, Amoxycillin with clavulanic acid Diclofenac inj, Nimulide Gelusil Perinorm susp (3) Ranitidine tablet, inj (20., Wysolin tablet, Furoxon, Iron preparations Cyproheptadine (syrup/tab), Methylcobalamine</p>
Vellore (7)	<p>OTC, cattle, S&G, pain, swelling & giddiness Levamisole, cattle, tremor, enteritis.</p>	<p>Haemaccel/Hestar Doxycycline, Clavulanic acid vomikind/vomiset, metaclopramide (2) Omeprazole, ranitidine, pantaprazole Diclofenac, paracetamol</p>
Villupuram (29)	<p>Nimesulide, cattle, abortion</p> <p>Procaine penicilline, cattle, died</p>	<p>Oxytocin (2), metaclopramide (2), nemocid (2),</p> <p>Avomin, loperamide Ceftriaxone, Toxim inj (2), Ciprofloxacin, Ofloxacin, Metrogyl</p>

	OTC IV inj, cattle, respiratory distress-asphyxia, pain swelling (2) Sulphadiazine i.m inj, cattle, skin eruption Triamcinolone acetate, cattle, salivation, erythema, eruptions, respiratory distress Paracetamol, cattle, nervous symptoms Hivit, cattle, allergy Tetramisole, cattle, nervous symptoms E care Se, dog, allergic reactions Multivitamin, cattle, Anorectic, salivation Levamisole, sheep/goat, sudden fall, death Oxytocin, cattle, animal died after 4 days	Magsulf IV for tetanus Sodiumbicarbonate IV for acidosis Diclofenac (3), paracetamol Cyanocobalamine, Insulin, Dexorange Digene/gelusil (2), Ranitidine inj Placentrix (human placental extract) Thiopentone sodium Vincristine/cytocristin Drez solution ORS electrolytes in dog Homeopathy - Phytolaceaberry pills, Tuja pills
Virudhunagar (2)	Livodex inj, cattle, nervous symptoms Phosphorus, cattle, dyspnoea	Avomin, perinorm, emiset Neurobion Lomofen, Metrogyl Diclofenac (2), Avil Gentamicin, Ciplox-TZ (i/u route)
TOTAL RESPONDANTS	172	

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